In re: National Prescription Opiate Litigation MDL no. 2804
Case No. 17-md-2804
Pharmacist Expert Supplemental Opinion
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Contents

Executive Summary

This supplemental report provides my opinions regarding the usual and customary practice of pharmacy and pharmacy practices of CVS, Walgreens, Walmart, Rite Aid, and Giant Eagle as determined by my review of documents provided to and requested by me.[1] Where applicable, this report refers to CVS, Walgreens, Walmart, Rite Aid, and Giant Eagle collectively as "Defendants" or the "Chain Pharmacies."

The issues examined specifically concern Defendants' actions with respect to maintaining effective policies and practices to guard against the diversion of prescription opioids, their failure to maintain and adhere to well-established pharmacy standards of care, and their dispensing of opioids into Lake and Trumbull Counties despite obvious and significant red flags.

A summary of my opinions is below:

- The practice of pharmacy is governed by well-defined laws and regulations, both at the national and state-wide levels.
- The practice of pharmacy is subject to established and well-known standards of care, including requirements for the careful evaluation of prescriptions and efforts to guard against the diversion of medications into non-medical or illegitimate use.
- Federal and Ohio State controlled substances laws and regulations require Defendants to maintain effective controls for a closed system of distribution and dispensing of opioids that guards against diversion.
- Corporate oversight includes established practices of pharmacies that should incorporate top-down compliance programs using data readily available to the corporation to guard against diversion. Oversight also should support, and not impede, pharmacists in complying with laws and regulations related to the dispensing of controlled substances.
- Corporate oversight should set patient care and integrity expectations and provide tools for pharmacists to exercise practices to adhere to appropriate laws, regulations, and pharmacy standards of care in dispensing controlled substances.
- Defendants were and remain aware of these requirements.
- Defendants failed to timely implement and apply necessary controlled substance diversion policies across their pharmacy stores.
- Once controlled substances diversion policies were developed, Defendants failed to monitor and enforce the policies across their pharmacy stores.

[1] Supplements to the report were made to comply with the court's May 10, 2021 Order, Doc # 3726 and to include two additional sources that only became available after my initial reported was submitted.

- Defendants implemented employment evaluation policies and performance metrics that impeded their pharmacists' efforts to comply with laws and regulations and meet standards of care.
- Defendants' local stores filled thousands of prescriptions presenting red flags without evidence of resolving those red flags.
- Defendants and their pharmacists have a corresponding responsibility to only fill prescriptions for controlled substances that are issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his/her professional practice.
- Defendants' performance metrics and pharmacy operations financial incentives hampered the ability of pharmacists employed by the Chain Pharmacies to maintain effective controls to guard against the diversion of controlled substances through Defendants' pharmacies.
- Defendants failed to provide their pharmacists with data, information and the tools necessary to assist their pharmacists in fulfilling their corresponding responsibility duties, including but not limited to, utilizing dispensing data to identify patterns, trends, and practitioners possibly involved in diversion as well to recognize and resolve red flags. The subsequent result of the failure to provide such data, information, and tools was the diversion of significant quantities of controlled substances, particularly opioids, outside of the closed distribution and dispensing system for controlled substances.

I offer my opinions herein to a reasonable degree of professional certainty. Based on the totality of the circumstances, it is my opinion that the Defendants failed to maintain effective controls to guard against diversion. My opinion is based upon the review of Defendants' policies, procedures and practices as well as the dispensing data that each defendant provided and which demonstrated that Defendants' dispensed thousands of controlled substances in the presence of known red flags. The dispensing of prescriptions without the resolution of obvious and known red flags did not meet the required pharmacy practice and regulatory standards for dispensing controlled substances resulting in a widespread failure to maintain effective controls to guard against the diversion of controlled substances. I reserve the right to supplement this report if new information becomes available.

Introduction

The opinions presented are based on my experience and expertise in the practice and regulation of pharmacy. From 1988 to 2020, I served as the Executive Director and the CEO of the National Association of Boards of Pharmacy (NABP). NABP was established as an impartial organization in 1904. The members of NABP are the state agencies that regulate the practice of pharmacy. NABP supports the state boards of pharmacy by developing, implementing, and enforcing uniform standards for the purpose of protecting the public health. NABP also helps state boards of pharmacy protect public health and safety through its pharmacist license transfer, pharmacist competence assessment, and accreditation programs. As Executive Director I oversaw the day-to-

day operations of the NABP. A significant focus of my work was in the area of pharmacy regulations through state boards of pharmacy and other governmental and private entities responsible for regulating pharmacists, technicians, pharmacies, wholesale distributors, and other entities in the pharmaceutical supply chain.

I previously served as liaison to the Food and Drug Administration (FDA) and the Drug Enforcement Agency (DEA). I served as a Governor of the Pharmacy Technician Certification Board (PTCB) and Chair of the PTCB Certification Council. I am also a Past President of the National Pharmacy Manpower Project and the National Conference of Pharmaceutical Organizations (NCPO) as well as a past member of the United States Pharmacopeia (USP) Board of Trustees.

I have been the recipient of many honors and awards including an Honorary Doctor of Pharmacy from the State of Oklahoma, the Certificate of Appreciation from the District of Columbia, two Food and Drug Administration (FDA) Commissioner Special Citations, the University of Illinois Alumnus of the Year, American Druggist Magazine Pharmacist of the Year, and the University of Illinois, College of Pharmacy, Alumni Association's Sister Margaret Wright Graduate Award.

I received a Bachelor of Science degree in pharmacy and a Master of Science degree in pharmacy administration from the University of Illinois at Chicago.

I have been recognized as an expert witness in state and federal district course numerous times. In the past fifteen years I have testified as an expert witness in the following litigations:

Trial: Expert Witness USA Office-Eastern District of Michigan, US v. Abiodun Fabode, October 30, 2019. Matter: Distribution of controlled substances.

Trial: Expert Witness USA Office-Southern District of New York, US v Lena Lasher, May 8, 2015. Matter: Distribution of prescription drugs over the internet.

Trial: Expert Witness USA Office-Southern District of New York, US v Lee, et al, September 10, 2014. Matter: Distribution of controlled substances.

Trial: Expert Witness USA Office-Northern District of Ohio, US v Rovedo, et al, October 10, 2012. Matter: Distribution of controlled substances.

Trial: Expert Witness USA Office-Northern District of California, San Francisco Division, US v Napoli, et al, October 4, 2012. Matter: Distribution of controlled substances.

Trial: Expert Witness USA Office-Northern District of California, San Francisco Division, US v Michael Arnold & Jeffrey Herholz, February 16, 2012.

I have provided testimony in the following United States Department of Justice Drug Enforcement Administration (DEA) hearings:

Trial: Expert Witness USA Office-Eastern District of Michigan, US v. Abiodun Fabode, October 30, 2019. Matter: Distribution of controlled substances.

Trial: Expert Witness USA Office-Southern District of New York, US v Lena Lasher, May 8, 2015. Matter: Distribution of prescription drugs over the internet.

Trial: Expert Witness USA Office-Southern District of New York, US v Lee, et al, September 10, 2014. Matter: Distribution of controlled substances.

Trial: Expert Witness USA Office-Northern District of Ohio, US v Rovedo, et al, October 10, 2012. Matter: Distribution of controlled substances.

Trial: Expert Witness USA Office-Northern District of California, San Francisco Division, US v Napoli, et al, October 4, 2012. Matter: Distribution of controlled substances.

Trial: Expert Witness USA Office-Northern District of California, San Francisco Division, US v Michael Arnold & Jeffrey Herholz, February 16, 2012. Matter: Distribution of controlled substances.

Trial: Expert Witness USA Office-District of Massachusetts, Boston Division, US v Baldwin Ihenacho, January 18, 2012. Matter: Distribution of prescription drugs over the internet.

Trial: Expert Witness USA Office-Eastern District of Texas, Beaumont Division, US v David Vogel, et al, June 30, 2010. Matter: Distribution of prescription drugs over the internet.

Trial: Expert Witness USA Office-Western District of Missouri, Western Division, US v Rostie, et al, June 28, 2010. Matter: Distribution of controlled substances.

Trial: Expert Witness USA Office-Western District of North Carolina, Charlotte Division, US v Woody, et al, August 17, 2009. Matter: Distribution of prescription drugs over the internet.

Trial: Expert Witness USA Office-Middle District of Florida, Orlando Division US v Jude LaCour, et al, April 14, 2009. Matter: Distribution of prescription drugs over the internet.

Trial: Expert Witness USA Office-Twentieth Judicial District of Kansas, Rice County: US v Hogan's Pharmacy, March 12, 2009. Matter: Distribution of prescription drugs over the internet.

Trial: Expert Witness USA Office-Eastern District of New York: US v Wahidullah Hossaini, November 12, 2008. Matter: Distribution and possession of oxycodone and hydrocodone.

Trial: Expert Witness USA Office-Eastern District of New York: US v Quinones, et al, October 27, 2008. Matter: Distribution of prescription drugs over the internet.

Trial: Expert Witness USA Office-District of Maryland: US v Steven A Sodipo, et al, July 7-8, 2008. Matter: Distribution of prescription drugs over the internet.

Trial: USA Office-Northern District of California: In the Matter of the Accusation Against: US v International Pharmaceutical Services Afshin Adibi, Respondent, November 28, 2007.

Trial: Expert Witness USA Office-District of Minnesota: US v Christopher Wm. Smith, November 15, 2006. Matter: Illegal distribution of prescription drugs.

Hearing: DEA In The Matter of: United Prescription Services, Inc, April 10, 2007. RE: Illegal distribution of controlled substances.

Hearing: DEA In The Matter of: Trinity Healthcare Corporation, d/b/a Oviedo Discount Pharmacy (No. 06-4), June 1, 2006. RE: Illegal distribution of controlled substances.

In addition to my experience, I have also reviewed numerous documents some of which formed the basis of the opinions offered in this report. A complete list of the materials I reviewed is attached as Exhibit A.

I am being compensated for my time at an hourly rate of $300.00. My compensation is not dependent on the outcome of this proceeding.

The Practice of Pharmacy – Standard of Care

The mission of pharmacy practice is "to serve society as the profession responsible for the appropriate use of medications, devices, and services to achieve optimal therapeutic outcomes."[2] The path to becoming a pharmacist involves years of specialized training, education and licensure and ongoing continuing education to remain current with new drugs, devices, therapies, and standards.

Standards of care define a competent level of care expected of a pharmacist dispensing medications and providing direct patient care. Standards of care direct and seek to maintain safe and clinically competent practitioners. Pharmacists are not mere sellers of tablets and capsules prescribed by doctors. They are licensed professionals with independent duties and obligations which have evolved over the past century. Those practices and their standard of care are reflected in national

[2] Vision and Mission for the Pharmacy Profession, American Pharmacists Association, adopted by the APhA House of Delegates (March 1991).

and state laws and regulations as well as pharmacy practice organizations and industry guidance. Moreover, pharmacists and pharmacies are entrusted with a key role in helping ensure that people achieve the best results from their medications.

The practice of pharmacy has developed into a fairly uniform standard of practice across the US. State and federal regulations setting forth state and national requirements across the states identify the responsibilities of the pharmacy and its agents (pharmacist and technicians) and desired patient outcomes uniformly with only limited variances in patient care and regulatory areas. In the usual and customary practice of pharmacy, a pharmacist must carefully evaluate every prescription presented for dispensing. The evaluation is a multi-component process that examines whether the prescription is appropriate and safe for the patient and, if issued for a controlled substance, there is an additional responsibility for a heightened evaluation to determine that the prescription is valid and issued for a legitimate medical purpose.

As discussed further below, the evaluation process begins with an assessment of the prescription to determine if it is appropriate and safe for the patient. The pharmacist is required to review the prescription in the context of patient factors (allergies, weight, etc.), reason for the issuance of the prescription (condition, diagnosis, and/or symptoms), medications the patient is currently using (to identify any potential adverse effects and adverse drug reactions or interactions, including ineffective drug therapy, significant side effects, significant drug interactions, over-utilization of a drug, duplicate drug therapy, and abuse, misuse or noncompliance with drug therapy), and applicable lifestyle factors (smoking, alcohol or drug use, etc.). This process is commonly referred to as Drug Utilization Review (DUR). It is also referred to as Drug Utilization Evaluation (DUE) or Medication Utilization Evaluation (MUE).

It has long been understood that dispensing drugs for non-medical purposes or which a pharmacist otherwise knows or should know present a significant risk for diversion falls outside the defined practice of pharmacy and standards of care. As part of their assessment, pharmacists must consider whether what is presented to them as a "prescription" is in fact valid and issued by a licensed professional in the usual course of professional practice. This common-sense requirement is codified into laws and regulations including, at the federal level, the Comprehensive Drug Abuse Prevention and Control Act of 1970 ("Controlled Substances Act" or "(CSA"), 21 U.S.C. §§ 801 *et. seq.*.) as well as pertinent state laws. *See* Ohio Admin. Code 4729-5-21(A). Among other requirements, a pharmacy registrant must provide effective controls and procedures to guard against theft and diversion of controlled substances. 21 C.F.R. 1301.71. For a controlled substance prescription to be valid, a pharmacist is obligated to determine whether the prescription was issued for a legitimate medical purpose. 21 C.F.R. 1306.04(a). A prescription for a controlled substance may only be filled by a pharmacist, *acting in the usual course of his professional practice* and either registered individually or employed in a registered pharmacy, a registered central fill pharmacy, or registered institutional practitioner (emphasis added). 21 C.F.R. 1306.06

Corporate Oversight

Pharmacies are permitted or licensed to operate with important responsibilities and duties in the practice of pharmacy. In exchange for the privilege of holding a license to distribute and dispense controlled substances, Pharmacies have the responsibility of ensuring that their controlled substances are not diverted and/or subject to abuse and misuse. Pharmacies have operating systems and methods to dispense, store, and retain prescriptions and prescription dispensing data and records. The information must be readily retrievable when requested by state authorities and utilized to identify patterns of diversion, audit the dispensing of their pharmacists, develop training programs and information for their pharmacy and management personnel, investigate suspicious prescribers, patients, and pharmacists, and prevent diversion of controlled substances. These responsibilities are reflected in the Controlled Substances Act and relevant Ohio state law. Those responsible include the pharmacist, technician, and the pharmacy. State regulations and the NABP Model Act define responsible entities as individuals, partnerships, corporations, associations, trusts, or other entities without qualification. Responsibilities extend to the hiring, training, and managing of pharmacy personnel as well as the supporting policies, procedures, and systems that promote public health and safety and assist in the identification and prevention of the diversion of controlled substances. The large Chain Pharmacies operate pharmacies in multiple states and employ thousands of pharmacists and pharmacy technicians who support pharmacists, in various roles.

Although Chain Pharmacies market their specific images and offer varying services, the infrastructure is quite similar. A chain pharmacy company is defined as operating more than four or more pharmacies which include traditional drug store formats as well as pharmacies located in supermarkets, mass merchant, and discount stores. Traditional chain drug stores tend to be much larger than independent drug stores with centralized operational processes – prescription processing, reimbursement submissions, product ordering and distribution, and policies and procedures.[3]

Individual pharmacies are managed by a store manager. The store manager is a salaried position with incentives based upon performance metrics established by the chain — typically, store performance, inventory, and customer satisfaction. Store managers have operational control of the store and all of its departments. The store manager is responsible to a supervisor (sometimes referred to as district or regional manager or leader) who oversees a number of stores within a shared geographic area or common division. The regional or district managers typically report directly to corporate liaisons.

Pharmacy chains exert a great deal of control over, and oversight of, their pharmacies and pharmacist employees which directly impacts the dispensing of controlled substances. Chain

[3] NACDS Chain Member Fact Book, 2019-2020.

pharmacy technicians, whose role has evolved over time, assist pharmacists through the completion of tasks including but not limited to accepting the prescription(s) from patients, entering the prescription information into the dispensing system, and assisting in the assessment of the validity of prescription(s). As a result, Chain Pharmacies and their agents are responsible "Persons" under the Controlled Substances Act. The chain pharmacy corporation through the control they exert over their agent pharmacies, pharmacists, and pharmacy employees, hold responsibility for ensuring all dispensing of controlled substances is carried out in accordance with applicable laws and regulations.

State law requires that every pharmacy be overseen by a pharmacist-in-charge or responsible pharmacist. The pharmacist-in-charge is accountable for the operation and management of the pharmacy within the required legal context of state and federal laws and regulations and corporate management and control. The pharmacist-in-charge is responsible to the store manager and a regional or district pharmacy manager. The regional or district pharmacy manager is responsible to a corporate liaison.

Chain Pharmacies have important responsibilities and duties in the practice of pharmacy. Chain Pharmacies are subject to a number of legal obligations, including those discussed in this report. A top-down compliance program which includes audits to determine whether written policies and procedures are being observed is important to ensuring that the pharmacy and its pharmacists are satisfying their obligations and meeting the applicable standard of care. Pharmacies must maintain systems and methods to store and retain prescription dispensing data and records. Documentation related to the dispensing of controlled substances is a critical component of any system or program. Documentation identifies critical factors, such as red flags, whether the pharmacist resolved the red flag(s), and information alerting to the occurrence or possibility of diversion. It also provides proactive direction to other pharmacists presented with the prescription going forward. Pharmacies must utilize their information to identify patterns of diversion, to audit the work of their pharmacists, to train its pharmacy personnel, investigate suspicious prescribers, patients, and pharmacists and to prevent diversion of controlled substances.

A pharmacy cannot absolve itself of its responsibilities under the CSA, particularly the "corresponding responsibility," discussed below, by placing unilateral responsibility on the pharmacist dispensing the prescription(s). A corporate chain pharmacy is also responsible for its operations including individual pharmacy stores and employees. Policies and procedures must be in place for all areas of operation related to controlled substances and the conduct of its pharmacy staff. The corporate entity is responsible for collecting and monitoring data related to the individual pharmacies and pharmacists and dispensing of controlled substances in order to comply with the CSA requirements outlined above and within state laws and regulations. The corporate chain pharmacy is also responsible for providing its pharmacy stores and employees access to databases, information, training and tools (utilizing whatever infrastructure necessary such as intranet and internet systems) to assist in determining the validity of a prescription such as whether a prescriber is appropriately licensed and other due diligence related to the filling and validity of a controlled substance prescription. [redacted]

[redacted]

Pharmacies must also ensure adequate staffing. This includes ensuring the presence of a licensed pharmacist at all times the pharmacy is operating, and appropriate staffing levels to safely and effectively evaluate and dispense medications and counsel patients. This standard is a legal requirement and encompasses additional requirements of the pharmacist-in-charge including but not limited to pharmacist coverage at all times the pharmacy is open and the ratio of pharmacists and pharmacy technicians. The requirements in Ohio are similar to the requirements across states:

> OH Rule 4729-9-02.
> Minimum standards for a pharmacy.
>
> (A) Library
>
> (1) All pharmacists working in a pharmacy must be able to access all current federal and state laws, regulations, and rules governing the legal distribution of drugs in Ohio;
> (2) The pharmacy shall have access to and utilize the references necessary to conduct a pharmacy in a manner that is in the best interest of the patients served and to comply with all state and federal laws; and
> (3) Telephone number of a poison control center.
>
> (B) Equipment
> The pharmacy shall carry and utilize the equipment necessary to conduct a pharmacy in a manner that is in the best interest of the patients served and to comply with all state and federal laws.
>
> (C) Stock of drugs
> The stock of drugs shall include such chemicals, drugs, and preparations sufficient to compound and prepare all types of prescriptions offered by the pharmacy.
>
> (D) Prescription containers
> The stock of prescription containers shall include such containers as are necessary to dispense drugs in accordance with federal and state laws, including the provisions of the federal Poison Prevention Act of 1970 and compendial standards, or as recommended by the manufacturer or distributor for non-compendial drug products.
>
> (E) Space and fixtures

[4] [redacted]

(1) The stock, library, and equipment shall be housed in a suitable, well-lighted and well-ventilated room or department with clean and sanitary surroundings primarily used for the compounding and preparing of prescriptions and for the manufacture of pharmaceutical preparations.

(2) All areas where drugs and devices are stored shall be dry, well-lighted, well-ventilated, and maintained in a clean and orderly condition. Storage areas shall be maintained at temperatures which will ensure the integrity of the drugs prior to their dispensing as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling unless otherwise indicated by the board.

(3) All storage areas shall provide adequate physical security for all dangerous drugs in accordance with rules 4729-9-05 and 4729-9-11 of the Administrative Code.

(F) Pharmacy hours

Notice to the public of operating hours of the pharmacy department must be posted.

(G) Personnel

The pharmacy shall be appropriately staffed to operate in a safe and effective manner pursuant to section 4729.55 of the Revised Code. An employee of a pharmacy that may have contact with patients or the general public must be identified by a nametag that includes the employee's job title.

(H) Additional minimum standards are required for specialized pharmacy practices pursuant to Chapters 4729-15, 4729-17, and 4729-19 of the Administrative Code.

History: 2013-14 OMR pam. # 11 (A), eff. 5-22-14; 2008-09 OMR pam. #6 (A), eff. 1-1-09; 2007-08 OMR pam. #6 (RRD); 2005-06 OMR pam. #6 (A), eff. 1-1-06; 2004-05 OMR pam. #4 (RRD); 1998-99 OMR 1613 (A), eff. 3-1-99; 1993-94 OMR 1160 (A), eff. 7-1-94; 1991-92 OMR 1311 (A), eff. 7-1-92; 1989-90 OMR 1139 (A), eff. 7-1-90; 1987-88 OMR 1162 (A-TF 4729-9-01), eff. 3-21-88; 1985-86 OMR 238 (R), eff. 9-1-85; prior PH-9-02.

Corporate pharmacy chain companies operate as diverse retail businesses and include among the responsibilities of their management and staff requirements or expectations that are not inherently or intuitively part of the practice of pharmacy in the traditional sense. These include various business goals such as the pace at which prescriptions are filled, including meeting promised wait time goals and the volume of sales or provision of additional promotional services such as immunizations and vaccinations. Pharmacy chains also set more directly revenue-related goals.

At times, these corporate goals obstruct the performance of pharmacists' professional obligations.[5] An example can be found in the inherent conflict between performance metrics that require pharmacists to fill certain volume of prescriptions or to limit customers' wait time and the pharmacist's ability to conduct appropriate due diligence on a prescription for controlled substances. In addition, basing pharmacists' incentive pay on customer satisfaction and the expected dissatisfaction that is likely to result from a pharmacist declining to fill a prescription due to deficiencies in the prescription or suspected diversion creates a disparity between the pharmacist's responsibility to ensure optimal patient outcomes and corporate business measures. There is also a duty to ensure compliance with the law through a corporate culture that directs and firmly supports pharmacists in exercising their professional judgment and discharging their legal responsibility to decline to fill and subsequently report prescriptions or other conduct that suggest diversion. Too often, pharmacists report being discouraged by management from raising concerns about prescribers or practices or declining prescriptions, or facing time and volume pressures or priorities that make compliance an impossible or devalued part of their job responsibilities.

Background Requirements

A. DUR Process

The pharmacist's historical role has been to serve as the medication therapy expert and assuring that the medication prescribed is appropriate for a particular condition or symptom. Ascertaining the appropriateness of a patient's medication therapy includes, for example, verifying that the dosage and duration of the treatment is correct for the condition and/or symptoms, does not conflict with the patient's allergies or individual characteristics such as metabolism rate, does not interact with other medications the patient is taking, and that the patient is not abusing or misusing the medication. These traditional roles and duties were codified for Medicaid beneficiaries with the passage of the Omnibus Budget reconciliation Act of 1990 (OBRA 90), and extended further beyond Medicaid beneficiaries by state pharmacy boards.

OBRA '90 added to the federal statutory requirements governing participation in the federal-state partnership program officially designated Grants to States for Medical Assistance Programs, and known in everyday parlance as the Medicaid program. The federal statute laid out responsibilities for pharmacies to ensure that prescriptions were appropriate for, and understood by, Medicaid

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[5] Munger Mark A.; Gordon, Elliot; Hartman, John; Vincent, Kristen; Feehan, Michael, *Community pharmacists' occupational satisfaction and stress: a profession in jeopardy?*, J. Am. Pharm. Assoc., May-Jun 2013; 53(3):282-96. DOI:10.1331/JAPhA.2013.12158.

beneficiaries. OBRA '90 had several major components: 1) Prospective Drug Use Review, 2) Retrospective Drug Use Review, 3) Assessment of Drug Use Data, and 4) Educational Outreach Programs.[6]

Implementing regulations governing drug use review came into effect on January 2, 1993, as an interim final rule. HHS's Health Care Financing Agency (HCFA), which oversees Medicaid, finalized the regulation on September 23, 1994. *See* 59 FR 48811-48825. The final rule requires "review of drug therapy before each prescription is filled or delivered to a recipient" for purposes of "detect[ing]" issues such as "therapeutic duplication, adverse drug-drug interaction," and "clinical abuse and/or misuse." The rule also mandates patient "[c]ounseling and maintenance of patient profiles by the pharmacist."

During the rulemaking process, "[o]ne commenter suggested that instructions for compliance with prospective DUR should go to the pharmacist and **not** the pharmacy." The government's response stated, "We believe that the instructions for compliance with prospective DUR should be directed to the pharmacies . . . . nothing that "[t]he owners or managers of pharmacies, as Medicaid providers, are responsible for furnishing their staff with information pertaining to DUR." *See*, p 48816, first column. States took action to require OBRA 90's mandates for the states to improve understanding of medications to all patients to assure uniformity of care and avoid establishing differing standards of care among patients.

A summary of the requirements is included in the Table below:[7]

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[6] Vivian, J.C., & Fink III, Joseph, *OBRA '90 at Sweet Sixteen: A Retrospective Review,* U.S. Pharmacist, March 20, 2008.

[7] *See id.*

Table 1

OBRA '90 Pharmacy Provisions

The primary focus of pharmacy activities required under OBRA '90 include:

Prospective Drug Utilization Review

Is the prescription necessary and appropriate? Factors to consider:

- Over/under utilization
- Therapeutic duplications
- Drug-disease interactions
- Drug-drug interactions
- Incorrect dosage or duration of treatment
- Drug-allergy interactions
- Clinical abuse and/or misuse

Patient Counseling Standards

An offer to have a pharmacist counsel the patient must be made. Items to address:

- Name of drug (brand name, generic, or other descriptive information)
- Intended use and expected action
- Route, dosage form, dosage, and administration schedule
- Common side effects that may be encountered, including their avoidance and the action required if they occur
- Techniques for self-monitoring of drug therapy
- Proper storage
- Potential drug-drug or drug-food interactions or other therapeutic contraindications
- Prescription refill information
- Action to be taken in the event of a missed dose

Maintaining Patient Records

Keep accurate and up-to-date patient profiles. Information to include:

- Patient's full name
- Address and telephone number
- Date of birth or age
- Gender
- Drug profile
- Pharmacist comments
- Chronic conditions, allergies, and drug reactions

The DUR process is a foundational component of the practice of pharmacy and defined by state practice acts and rules. It is also a key tenet of the standards of care for the practice of pharmacy. The DUR process has been a provision of the legal and standard of care requirements for pharmacy practice in Ohio before the enactment of OBRA 90. The Ohio Practice Act and Regulations in 2003 required the following for Prospective Drug Utilization Review:

A. Prior to dispensing any prescription, a pharmacist shall review the patient profile for the purpose of identifying:

1) Over-utilization or under-utilization;
2) Therapeutic duplication;
3) Drug-disease state contraindications;
4) Drug-drug interactions;
5) Incorrect drug dosage;
6) Drug-allergy interactions;
7) Abuse/misuse;
8) Inappropriate duration of drug treatment;
9) Documented food-nutritional supplements-drug interaction.

B. Upon recognizing any of the above, a pharmacist, using professional judgment, shall take appropriate steps to avoid or resolve the potential problem. These steps may include consulting with the prescriber and/or counseling the patient.

C. Prospective drug utilization review shall be performed using predetermined standards consistent with, but not limited to, any of the following:
   1) Peer-reviewed medical literature (that is, scientific, medical, and pharmaceutical publications in which original manuscripts are rejected or published only after having been critically reviewed by unbiased independent experts);
   2) American hospital formulary service drug information;
   United States pharmacopoeia drug information; American medical association evaluations.

The DUR process is especially important for the assessment of the appropriateness of prescribed controlled substances, such as opioids, which have a high propensity for abuse and addiction. Such an assessment should examine over-utilization, inappropriate duration of treatment, drug interactions, and therapeutic duplication in order to provide appropriate care and identify abuse and misuse of these dangerous drugs. Communities where opioids were readily available and prescribed liberally were the first areas to experience markedly increased opioid abuse.

Realizing that these general DUR provisions were not effectively preventing the escalation of opioid over-use and abuse, states revised and expanded practice acts and rules and increased their support for, and reliance on, Prescription Drug Monitoring Program (PDMPs) such as the Ohio Automated Rx Reporting System (OARRS) program.

A PDMP is an interactive database that facilitates the sharing of health information related to controlled substance prescriptions. PDMPs provide clinicians with information on a patient's controlled-substance prescription history and can be a useful tool when considering treatment options and screening patients who may at risk for abuse or diversion. Chain Pharmacies, along with independents, are the primary sources of the data contained within a PDMP and they play a critical role in ensuring that complete and comprehensive data is provided so as to contribute to the usefulness of the database.

The first PDMP program was enacted by New York State in 1918 and introduced to monitor prescriptions for cocaine, codeine, heroin, morphine, and opium. Pharmacists were required to

report copies of prescriptions to the New York State Health Department within 24 hours. California initiated its prescription monitoring program in 1939. The enactment began the "paper era" of PDMPs. In 1989, Oklahoma required that prescription monitoring data be communicated electronically. State PDMPs continued to grow through the 1990s and early 2000s, with 70% of program establishments occurring in the first 15 years of the 21st century.[8]

The majority of PDMP programs were established in the states around this time to help combat the growing opioid epidemic. Ohio's OARRS program was signed into law in May 2005 when the Ohio House of Representatives and Ohio Senate signed the necessary legislation.[9] OARRS went live on October 2, 2006. With the launching of the OARRS program, Ohio served as an early adopter and leader in the development and use of PDMPs.[10]

OARRS is a statewide electronic database which contains dispensing information on scheduled controlled substances, as well as any non-controlled substances for which the Ohio Board of Pharmacy requires information to be submitted into OARRS. Pharmacies submit prescription information into OARRS when a controlled substance is dispensed. As authorized users at the time OARRS was established, pharmacists could access this database before dispensing as a screening tool to assist in decision making by consulting the patient's prescription history in OARRS. The MDL Court has observed that, "'[t]he Ohio Automated Rx Reporting System (OARRS) is a tool to track the dispensing and personal furnishing of controlled prescription drugs to patients.'" *In re Nat'l Prescription Opiate Litig.*, 1:17-MD-2804, 2019 WL 763564, at *1 (N.D. Ohio Jan. 23, 2019) (quoting https://www.ohiopmp.gov/).

The Ohio Board of Pharmacy created a training video to demonstrate how OARRS may be accessed and used.[11] The CDC recognizes that:

> PDMPs improve patient safety by allowing clinicians to:
>
> Identify patients who are obtaining opioids from multiple providers.
>
> Calculate the total amount of opioids prescribed per day (in MME/day).

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[8] Prescription Drug Monitoring Program Training and Technical Assistance Center, *History of prescription drug monitoring programs,* Brandeis University (Mar. 2018), pdmpassist.org/pdf/PDMP_admin/TAG_History_PDMPs_final_20180314.pdf.
[9] Ohio 125th General Assembly, House Bill 377, April 20, 2004.
[10] *See* BOP_MDL502176 at 502181.
[11] State of Ohio Board of Pharmacy, *How to Read an OARRS Report*, YouTube (Aug. 25, 2015), https://www.youtube.com/watch?v=nPHm6tei2RU; State of Ohio Board of Pharmacy, *How to Run an OARRS Report*, YouTube (Aug. 25, 2015), https://www.youtube.com/watch?v=Pv8qX2pXrVw.

> Identify patients who are being prescribed other substances that may increase risk of opioids—such as benzodiazepines.
>
> Information in PDMPs is potentially life-saving and allows pharmacists to identify patients who may be misusing prescription opioids or at risk for overdose. [12]

Ohio revised their requirements in 2011 requiring pharmacists to review OARRS prior to dispensing a prescription involving red flags. Information in PDMPs is potentially life-saving, and allows pharmacists to identify patients who may be misusing prescription opioids or at risk for overdose.[13]

Prospective drug utilization review

A. Prior to dispensing any prescription, a pharmacist shall review the patient profile for the purpose of identifying:
    1. Over-utilization or under-utilization;
    2. Therapeutic duplication;
    3. Drug-disease state contraindications;
    4. Drug-drug interactions;
    5. Incorrect drug dosage;
    6. Drug-allergy interactions;
    7. Abuse/misuse;
    8. Inappropriate duration of drug treatment;
    9. Food-nutritional supplements-drug interactions.
B. Upon recognizing any of the above, a pharmacist, using professional judgment, shall take appropriate steps to avoid or resolve the potential problem. These steps may include requesting and reviewing an OARRS report or another state's report if applicable and available, and/or consulting with the prescriber and/or counseling the patient.
C. Prior to dispensing a prescription, at a minimum, a pharmacist shall request and review an OARRS report covering at least a one-year time period and/or another state's report, where applicable and available, if a pharmacist becomes aware of a person currently:
    1. Receiving reported drugs from multiple prescribers;
    2. Receiving reported drugs for more than twelve consecutive weeks;
    3. Abusing or misusing reported drugs (i.e. over-utilization, early refills, appears overly sedated or intoxicated upon presenting a prescription for a reported drug, or

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[12] CDC, Prescription Drug Monitoring Programs (PDMPs): What Healthcare Providers Need to Know, https://www.cdc.gov/drugoverdose/pdmp/providers.html.
[13] *Id*.

an unfamiliar patient requesting a reported drug by specific name, street name, color, or identifying marks);

4. Requesting the dispensing of reported drugs from a prescription issued by a prescriber with whom the pharmacist is unfamiliar (i.e. prescriber is located out-of-state or prescriber is outside the usual pharmacy geographic prescriber care area); or
5. Presenting a prescription for reported drugs when the patient resides outside the usual pharmacy geographic patient population.

After obtaining an initial OARRS report on a patient, a pharmacist shall use professional judgment based on prevailing standards of practice in deciding the frequency of requesting and reviewing further OARRS reports and/or other states' reports for that patient.[14]

As a CVS witness confirmed, at the time Ohio first offered it's PMP in 2011 with regulations to consult with PMP in specific situations, CVS did not have a written policy or provide clear guidance otherwise on its use.[15]

In 2015, with the opioid epidemic growing out of control, Ohio's DUR requirements were further updated to mandate that pharmacists review OARRS data prior to dispensing all drugs listed in rule 4729-37-02 of the Ohio Administrative Code (OAC) under specified conditions. Drugs in this listing include all of the federally scheduled controlled substances, and thus, all of the drugs detailed in the prescription dispensing data reviewed for this report.[16]

OAC 4729-37-02 provided:

A. Prior to dispensing an outpatient prescription for a reported drug as listed in rule 4729-37-02 of the Ohio Administrative Code, at a minimum, a pharmacist shall request and review an OARRS report covering at least a one-year time period, including a border state's information when the pharmacist is practicing in a county bordering another state if that state's information is available, in any of the following circumstances:
    1. A patient adds a different or new reported drug to their therapy that was not previously included;
    2. An OARRS report has not been reviewed for that patient during the preceding 12 months, as indicated in the patient profile;
    3. A prescriber is located outside the usual pharmacy geographic area;

[14] OAC 4729-5-20.
[15] Travassos Dep. 295:3-10, April 14, 2021.
[16] OAC 4729-5-20; Exhibit 5 to Joyce Dep., Feb. 26, 2021.

4. A patient is from outside the usual pharmacy geographic area;
5. A pharmacist has reason to believe the patient has received prescriptions for reported drugs from more than one prescriber in the preceding 3 months, unless the prescriptions are from prescribers who practice at the same physical location;
6. Patient is exhibiting signs of potential abuse or diversion. This includes, but is not limited to, over-utilization, early refills, appears overly sedated or intoxicated upon presenting a prescription for a reported drug, or an unfamiliar patient requesting a reported drug by specific name, street name, color, or identifying marks.

The DUR process and state PDMPs are key instruments for pharmacies to identify and prevent diversion.

Each of the Defendants recognized the important role PDMPs play in identifying and analyzing potential signs of diversion. CVS characterized PDMPs like OARRS to be an "invaluable tool for Pharmacists to prevent controlled substances from being diverted or dispensed for non-medical purposes. . ." and they "cut down on prescription fraud and "doctor shopping" by providing Prescribers and Pharmacists with more complete information about a patient's controlled substance prescription history."[17] As rates of PDMP participation increase, measures of doctor shopping and prescribing of certain controlled substances decline. The data suggest that PDMP utilization helps to promote medically warranted prescribing and dispensing, and assists in detecting possible controlled substance misuse and diversion.[18]

B. Controlled Substances

Controlled substances are drugs which pose a significant risk to the public. Given the dangerous nature of these drugs, pharmacy practice dictates that several controls be put in place to secure these drugs and to ensure that they are dispensed only to patients holding a valid prescription, issued by a DEA licensed prescriber, and issued for a legitimate medical purpose by a practitioner acting within the usual course of the practitioner's professional practice. Providing prescription drugs for non-medical purposes or which present significant risk for diversion is not considered part of the practice of pharmacy.

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[17] CVS-NYAG-000010773, ROPP-0062 Prescription Drug Monitoring Policy (2015).
[18] PDMP Center of Excellence, *Mandating PDMP participation by medical providers: current status and experience in selected states*, Brandeis University (Feb. 2014).

1. The CSA

In addition to the above requirements and standards of care, the regulation of the practice of pharmacy includes specific provisions for the manufacture, importation, possession, use and distribution of controlled substances. Controlled substances require more stringent requirements and regulations than those for non-controlled substances because of the potential for abuse, harm, and diversion. The CSA was signed into law on October 27, 1970, effective May 1, 1971 to address the need for these more stringent considerations and to regulate all participants in the controlled substances' supply chain. The CSA contains three titles: Title I that addresses rehabilitation programs for individuals who abuse controlled substances, Title II that defines and outlines the processes for the registration and distribution of controlled substances, and Title III that concerns the importation and exportation of controlled substances. All state Pharmacy Practice Acts and Regulations incorporate the CSA and include additional state requirements for circumstances unique to a state.

The purpose of the CSA is "to improve the manufacturing, importation and exportation, distribution, and dispensing of controlled substances and to prevent the diversion, and the illegal misuse, of controlled substances. Entities involved in the manufacture, distribution, and dispensing of controlled substances must register with the DEA. Registration of these entities with the DEA results in the formation of a closed and comprehensive system for controlled substances distribution. This closed system allows for controlled substances to be traced from initial manufacture to final dispensing to the patient."[19] Every entity, registrant and agents of a registrant in the supply chain bears responsibility for preventing the misuse of controlled substances.

Maintaining a closed system for controlled substances which provide effective controls to guard against diversion is a vital public health concern. Prescription opioid medications are recognized as posing a high degree of risk from abuse and diversion.[20] As the last line of defense, pharmacies and pharmacists must ensure that prescriptions for controlled substances are issued for legitimate medical purposes, within the scope of the prescriber's practice, and not being abused or diverted. Corporate Chain Pharmacies exert tremendous control over policies and procedures at their stores and have an obligation to ensure their operation of stores and management of pharmacist employees supports their agents in maintaining effective controls to guard against diversion Failure to exercise this responsibility places dangerous drugs outside of the closed system mandated by the CSA and state requirements, with the risk of significant harm and death.

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[19] *See also* 21 C.F.R. § 801(2).

[20] Rachel N. Lipari & Arthur Hughes, *How People Obtain the Prescription Pain Relievers They Misuse*, CBHSQ Report, National Survey on Drug Use and Health (Jan. 12, 2017).

C. Schedules of Controlled Substances

Under the CSA, drugs, substances, and certain chemicals used to make drugs are classified into five (5) distinct categories or schedules depending upon the drug's accepted medical use and the drug's abuse or dependency potential. The abuse rate is a determinate factor in the scheduling of the drug; for example, Schedule I drugs have a high potential for abuse and the potential to create severe psychological and/or physical dependence. As the drug schedule changes-- Schedule II, Schedule III, etc., so does the abuse potential-- Schedule V drugs represent the least potential for abuse. See 21 C.F.R. Sections 1308.11 through 1308.15.

Schedule I

Schedule I drugs, substances, or chemicals are defined as drugs with no currently accepted medical use and a high potential for abuse. Some examples of Schedule I drugs are: heroin, lysergic acid diethylamide (LSD), marijuana (cannabis), 3,4-methylenedioxymethamphetamine (ecstasy), methaqualone, and peyote.

Schedule II

Schedule II drugs, substances, or chemicals are defined as drugs with a high potential for abuse, with use potentially leading to severe psychological or physical dependence. These drugs are also considered dangerous. Some examples of Schedule II drugs are: combination products with less than 15 milligrams of hydrocodone per dosage unit (Vicodin[21]), cocaine, methamphetamine, methadone, hydromorphone (Dilaudid), meperidine (Demerol), oxycodone (OxyContin), fentanyl, Dexedrine, Adderall, and Ritalin.

Schedule III

Schedule III drugs, substances, or chemicals are defined as drugs with a moderate to low potential for physical and psychological dependence. Some examples of Schedule III drugs are: products

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[21] US Department of Health and Human Services (HHS) on December 16, 2013, submitted to the Administrator of the DEA its scientific and medical evaluation entitled, "Basis for the Recommendation to Place Hydrocodone Combination Products in Schedule II of the Controlled Substances Act." Pursuant to 21 U.S.C. 811(b), this document contained an eight-factor analysis of the abuse potential of HCPs, along with the HHS's recommendation to control HCPs in schedule II of the CSA. Effective October 6, 2014, the Administrator of the DEA rescheduled hydrocodone combination products from schedule III to schedule II of the Controlled Substances Act. Federal Register Volume 79, Number 163 (Friday, August 22, 2014)], [Rules and Regulations], [Pages 49661-49682], From the Federal Register Online via the Government Printing Office [www.gpo.gov], [FR Doc No: 2014-19922].

containing less than 90 milligrams of codeine per dosage unit (Tylenol with codeine), ketamine, anabolic steroids, testosterone.

Schedule IV
Schedule IV drugs, substances, or chemicals are defined as drugs with a low potential for abuse and low risk of dependence. Some examples of Schedule IV drugs are: Xanax, Soma, Darvon, Darvocet, Valium, Ativan, Talwin, Ambien, Tramadol.

Schedule V
Schedule V drugs, substances, or chemicals are defined as drugs with lower potential for abuse than Schedule IV and consist of preparations containing limited quantities of certain narcotics. Schedule V drugs are generally used for antidiarrheal, antitussive, and analgesic purposes. Some examples of Schedule V drugs are: cough preparations with less than 200 milligrams of codeine or per 100 milliliters (Robitussin AC), Lomotil, Lyrica, Parepectolin.[22]

D. Registrant Requirements

Federal and state regulations clearly define the requirements for DEA registrants within the closed distribution system established by the CSA. A DEA registrant and its agents are wholly responsible for requirements of the CSA and state and federal requirements for controlled substances. Under the CSA and state regulations, pharmacy registrants are required to "provide effective controls and procedures to guard against theft and diversion of controlled substances." *See* 21 C.F.R. § 1301.71(a). The CSA creates a "closed system" of distribution in which distribution may lawfully occur only among registered handlers of controlled substances, referred to as "registrants." *See* DEA, 75 Fed. Reg. 16235, 16237 (Mar. 31, 2010).

As a former DEA diversion investigator, Demetra Ashley, whose testimony is also referenced above, agreed in testimony recorded in a transcript that I was provided, the five corporate defendants in this case have an obligation to provide effective controls and procedures to guard against theft and diversion of controlled substances.[23] Based on her years of experience, Ms. Ashley testified that it was her understanding that "a pharmacy and its pharmacists" have a responsibility to fill only opioid prescriptions that are issued for a legitimate medical purpose.[24]

All DEA pharmacy registrants are also required to maintain complete and accurate inventories and records of all regulated transactions involving controlled substances and listed chemicals, as well as provide adequate security controls to prevent their diversion. The closed system created and

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[22] *Id.*
[23] Ashley Dep. 104-107, Mar. 11, 2021.
[24] *Id.* at 134-35.

mandated by the CSA ensures that controlled substances are under the control of a DEA-registered Person until they reach the patient or are destroyed, and the CSA's regulatory requirements "ensure that all controlled substances are accounted for from their creation until their dispensing or destruction." *See* DEA, Definition and Registration of Reverse Distributors, 70 Fed. Reg. 22591 (May 2, 2005).

Compliance obligations for DEA registrants, pharmacies and their agents, focus on critical areas of practice such as inventory, security, record-keeping, prescription management and fraud monitoring, ordering, and dispensing / diversion prevention. Guidance issued by and actions taken by the DEA identified the aforementioned critical areas and provided clarification of the design and implementation of effective controls and compliance programs. Examples include but are not limited to:

- Procedures to identify the common signs associated with the diversion of controlled substances;
- Routine and periodic training of all pharmacy employees responsible for dispensing controlled substances on the elements of the compliance program and their responsibilities under the CSA;
- A System to notify the local DEA office of a refusal to fill a prescription for controlled substances where such refusal is based on the pharmacist's determination that the prescription was forged, altered, and/or issued for other than a legitimate medical purpose by a practitioner acting outside the usual course of professional practice;
- Policies and procedures to ensure that prescriptions for controlled substances are only dispensed to authorized individuals pursuant to federal and state law and regulations;
- Not knowingly dispensing an invalid prescription or a prescription that the pharmacist reasonably believes was issued for other than a legitimate medical purpose or by a practitioner acting outside the usual course of professional practice;
- A System to provide reports of dispensing upon request;
- A System to assess the data and other information available to the pharmacy and to notify dispensing pharmacists of potentially suspicious prescribers and prescriptions;
- A System to only dispense early fills of controlled substances in Schedules III-V that are valid and appropriately authorized; and
- A System to identify and prevent early fills of controlled substances.

Within the usual and customary practice of pharmacy, the CSA translates that a pharmacist must carefully evaluate every prescription for a controlled substance presented for dispensing. The evaluation requires a determination as to whether the prescription is valid and, the validity of a prescription for a controlled substance must be determined before dispensing. The determination requires the pharmacist to ascertain that the prescription was issued by a medical practitioner adhering to the usual course of his or her professional practice, the prescription is for a legitimate medical purpose, any red flag(s) are identified and resolved, there is a bona-fide relationship

between the prescriber and patient, and the possibility of abuse, diversion, or fraud has been investigated and addressed.

E. Corresponding Responsibility

A primary tenet of the standard of care in the practice of pharmacy is a pharmacist's independent responsibility to ensure that all prescriptions are issued for a legitimate medical purpose by a practitioner authorized by law while acting in the usual course of his professional practice. This duty is also set forth in the CSA and state practice acts and rules. The regulations expressly define and outline the corresponding responsibility of a pharmacist dispensing controlled substances. That responsibility can be summarized as explained above - requiring a pharmacist to determine if a prescription is valid and issued for a legitimate medical purpose by a practitioner authorized by law while acting in the usual course of his professional practice.

The CSA (21 C.F.R. § 1306.04) and additional guidance documents issued by the DEA also note the following: "The practitioner is responsible for the proper prescribing and dispensing of controlled substances. The pharmacist also has a corresponding responsibility regarding the dispensing of a prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is an invalid prescription within the meaning and intent of the CSA. The person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances."

Under 21 C.F.R. § 1306.06, "[a] prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice . . .." As the Department of Justice's recent lawsuit against Walmart alleges, 21 C.F.R. § 1306.06 "requires that a pharmacist's conduct, when filling controlled-substance prescriptions" adhere to the "usual course" of a pharmacist's professional practice." Complaint, *United States of America v. Walmart Inc. et al.*, 1:20-cv-01744, (D. Del. Dec. 22, 2020) at ¶ 88. The obligation to "identify any red flags" relating to a controlled-substances prescription, "to resolve them before filing the prescription, and to document any resolution of red flags" is "a well-recognized responsibility of a pharmacist in the professional practice of pharmacy." *Id.* Former DEA diversion investigator Demetra Ashley confirmed this proposition in her testimony.[25] When "Walmart pharmacists failed to comply with their own professional pharmacy standards" in this respect, "Walmart... violated 21 C.F.R. § 1306.06. *Id.* at ¶ 112.

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[25] Ashley Dep. 137:7-15.

The CSA clearly places the duty to prevent diversion upon each person and entity involved in dispensing controlled substances. The CSA and its implementing regulations hold accountable the registrant, manufacturer, distributor, pharmacy, and pharmacist who ultimately dispensed the prescription. Importantly, corresponding responsibility is a shared responsibility of the pharmacy and pharmacist and not the pharmacist alone.[26] Pharmacies have an important and crucial role in creating systems and programs to identify and prevent the filling of controlled substance prescriptions issued by prescribers for reasons such as not being appropriately licensed, and licenses expired or suspended. The pharmacy also has an important duty to create a system to identify critical components of the evaluation process, such as the prescriber's specialty and his scope of practice and the prescriber's prescribing patterns, in order for the prescription to be evaluated and determined whether the prescription is valid and written within the usual course of the prescriber's practice and for a legitimate medical purpose. The pharmacy has data that the pharmacist does not have access to, which should be used to identify red flags that are indicia of potential diversion and to share that information with the pharmacies' agents and employees. The pharmacy has an obligation to provide clear guidance through policies, procedures and training relating to corresponding responsibility and to create systems and programs to monitor the pharmacy to ensure that the policies, procedures and training are being followed.[27]

"The corresponding responsibility to ensure the dispensing of valid prescriptions extends to the pharmacy itself."[28] The *Holiday* decision was not the first DEA decision to hold pharmacies responsible for failing to fulfill their corresponding responsibility under the CSA, similar opinions were issued in *Medicine Shoppe-Jonesborough* and *United Prescription Services, Inc.*[29] The DEA has consistently held the pharmacy corporation, including Defendants in this litigation, responsible for failing to exercise its corresponding responsibility under the CSA.

Corresponding responsibility is also identified and defined in the DEA's publication—The Pharmacist's Manual An Informational Outline of the Controlled Substances Act and Actions (administrative and criminal) - Revised 2010.

> SECTION IX – VALID PRESCRIPTION REQUIREMENTS To dispense controlled substances, a pharmacist must know the requirements for a valid prescription which are

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[26] *Holiday CVS, LLC, d/b/a/ CVS Pharmacy Nos. 219 and 5195*, Decision and Order, Fed Reg. Vol. 77, No. 198, p. 62316-62346, at 62341 (October 12, 2012) ("*Holiday CVS*").

[27] A former DEA diversion investigator, whose testimony is also referenced above, agreed in a deposition in this case that as part of their obligation under Section 1301.71, pharmacies corporately have an obligation to develop policies to train pharmacists to comply the CSA regulations. *See* Ashley Dep. 123-24. Ms. Ashley further agreed that the defendants had an obligation to develop and implement systems to provide the necessary tools for their pharmacists to comply with the CSA regulations. *Id.*

[28] *Holiday CVS,* Fed Reg. Vol. 77, No. 198, at 62341.

[29] 73 FR 364, 384 (2008); 72 FR 50397, 50407-08 (2007).

> described in this section. A prescription is an order for medication which is dispensed to or for an ultimate user.
>
> Corresponding Responsibility
>
> A pharmacist also needs to know there is a corresponding responsibility for the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is an invalid prescription within the meaning and intent of the CSA (21 U.S.C. § 829). The person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.
>
> A pharmacist is required to exercise sound professional judgment when making a determination about the legitimacy of a controlled substance prescription. Such a determination is made before the prescription is dispensed. The law does not require a pharmacist to dispense a prescription of doubtful, questionable, or suspicious origin. To the contrary, the pharmacist who deliberately ignores a questionable prescription when there is reason to believe it was not issued for a legitimate medical purpose may be prosecuted along with the issuing practitioner, for knowingly and intentionally distributing controlled substances. Such action is a felony offense, which may result in the loss of one's business or professional license (see *United States v. Kershman*, 555 F.2d 198 [United States Court of Appeals, Eighth Circuit, 1977]).

The CSA and state laws inform the pharmacist that he is not required to dispense a prescription of doubtful, questionable, or suspicious origin. To the contrary, the pharmacist who deliberately ignores a questionable prescription when there is reason to believe it was not issued for a legitimate medical purpose may be prosecuted along with the issuing practitioner, for knowingly and intentionally distributing controlled substances.

A pharmacist who "filled a prescription notwithstanding her actual knowledge that the prescription lacked a legitimate medical purpose" or who "was willfully blind or deliberately ignorant to the fact that the prescription lacked a legitimate medical purpose" violates the corresponding responsibility requirement. *Pharmacy Doctors Enterprises*, 83 Fed. Reg. 10,876, 10,896 (DEA Mar. 13, 2018).

A pharmacist was found to have illegally dispensed controlled substances when the pharmacist "deliberately closed his eyes to the true nature of the prescription." *United States v. Lawson*, 682 F.2d at 482.

"Red Flags"

A pharmacist's corresponding responsibility and determination of whether a prescription issued for a controlled substance is valid and legitimate, requires systems and actions to recognize, investigate, and resolve signs of a prescription's invalidity (red flags) "arising during the presentation of a prescription which creates a reasonable suspicion that the prescription is not, on its face, legitimate."[30] Red flags are warning signs and can also indicate activities are occurring outside the usual and customary scope of pharmacy practice, activities that are more than likely to include abuse, diversion, and fraudulent acts. Walgreens witness Bryan Joyce succinctly stated that a red flag means "you need to stop and get more information."[31]

Red flags are not a novel or unknown concept to pharmacists, pharmacies, or pharmacy chains. Red flags are common sense warning signs that have always been an important component of controlled substance pharmacy best practices. In addition, at least since the 1930's and 1940's there has been guidance given to pharmacies and pharmacists related to the creation of systems and programs to guard against diversion and lists of don'ts when dispensing narcotics.[32]

Pharmacists have been trained when determining whether to fill a prescription for a controlled substance to be alert for suspicious activities surrounding the prescription. Licensed or registered pharmacists in every state are required to complete a formal education program of didactic and practical experience.

In addition to all pharmacists completing formal education programs, every state requires pharmacists to complete a state law or jurisprudence examination to qualify for licensure or transfer an existing license. In 2010 and continuing to 2019, 48 states, including Ohio, required NABP's Multistate Jurisprudence Examination (MPJE).[33] A validation study of the MPJE conducted in 2010 determined that the application of pharmacy law within the practice of pharmacy required increased emphasis on pharmacy jurisprudence as it applies to the practice of pharmacy. The emphasis included corresponding responsibility and red flags.[34]

Red Flags of diversion are known or should be known to pharmacists in the usual and customary practice of pharmacy. As noted above, red flags are known concepts in pharmacy practice and the

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[30] *United States v. City Pharmacy, LLC*, No. 3:16-CV-24, 2017 WL 1405164, at *4 (N.D. W.Va. Apr. 19, 2017); *see also United States v. Lawso*n, 682 F.2d 480, 483 n.6 (4th Cir. 1982).
[31] Joyce Dep. 180:4-5.
[32] *See*, Prescribing and Dispensing Narcotics Under the Harrison Narcotic Law, Pamphlet 56, U.S. Treasury Dep't, U.S. Bureau of Narcotics, (July 1938); Treasury Department, U.S. Bureau of Narcotics, late 1940s, "Narcotics 'DON'TS' for the Pharmacist," n.d., "Demerol," FBN Papers (IMG_3801).
[33] Idaho removed the state law requirement in 2019.
[34] NABP MPJE Competency Statements 2016.

regulation of pharmacy practice as well as the subject of DEA guidance, guidance from State Boards of Pharmacy, negotiated consensus documents published by the National Association of the Boards of Pharmacy, and by industry trade groups such as the National Association of Chain Pharmacies. Videos have also been created to give guidance to pharmacies and pharmacists on red flags of diversion.[35] Red Flags have also been the subject of numerous DEA diversion investigations, registration suspensions and revocations, and criminal and civil legal actions.

The performance of the red flag analysis required by the pharmacy's corresponding responsibility was especially critical when those in the practice of pharmacy became aware that opioid diversion and misuse reached epidemic proportions. The Centers for Disease Control and Prevention reported that: "In 2007, nearly 100 persons per day died of drug overdoses in the United States. The death rate of 11.8 per 100,000 population in 2007 was roughly three times the rate in 1991. Prescription drugs have accounted for most of the increase in those death rates since 1999. In 2009, 1.2 million emergency department (ED) visits (an increase of 98.4% since 2004) were related to misuse or abuse of pharmaceuticals, compared with 1.0 million ED visits related to use of illicit drugs such as heroin and cocaine. Prominent among these prescription drug--related deaths and ED visits are opioid pain relievers (OPR), also known as narcotic or opioid analgesics, a class of drugs that includes oxycodone, methadone, and hydrocodone, among others. OPR now account for more overdose deaths than heroin and cocaine combined. OPR frequently are diverted for nonmedical use by patients or their friends or sold on the street. In 2010, 4.8% of the U.S. population aged ≥12 years used OPR nonmedically. Nonmedical use of OPR costs insurance companies up to $72.5 billion annually in health-care costs.[36]

According to the CDC, as of 2019, nearly 841,000 people have died since 1999 from a drug overdose. The number of drug overdose deaths increased by nearly 5% from 2018 to 2019 and has quadrupled since 19991. Over 70% of the 70,630 deaths in 2019 involved an opioid.

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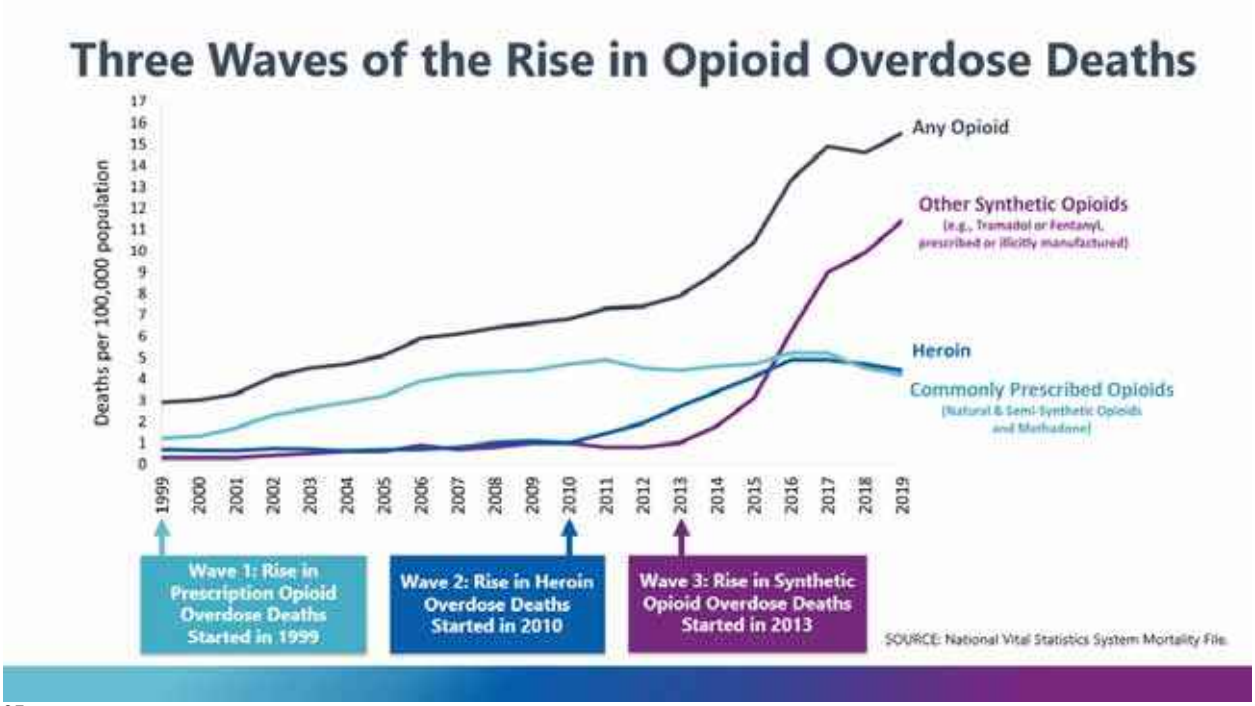
[35] "Red Flags," NABP Video produced by the Anti-Diversion Industry Working Group (May 20, 2014).
[36] Centers for Disease Control and Prevention (CDC), V*ital Signs: Overdoses of Prescription Opioid Pain Relievers --- United States, 1999--2008*, Weekly (Nov. 4, 2011).



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Defendant internal documents recognized the ongoing and growing prescription opioid epidemic beginning in the mid to late 2000's. And the Defendants' own policies, procedures and training materials began to contain lists red flags of diversion for controlled substances. However, while Defendants eventually recognized red flags in their policies, they were slow to do so, and such recognition occurred long after the misuse of opioids was well known and the opioid crisis had become an epidemic. [redacted] Giant Eagle did not acknowledge the red flags in their compliance policies until 2013 and later. Other than the red flags for large quantities and an alert for early refills, Walmart's policies (called "POMs") did not recognize most red flags until 2015 when it included, for the first time, the term "red flags" it its POM 1311.[38] CVS described prescriptions of concern following its meeting with the DEA in 2010 but did not have a policy outlining most of the red flags until 2012[39] and a more complete version in 2014.[40] Walgreens also included some of the red flags beginning in 2011 and 2012 following the DEA's suspension order.[41]

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[37] Centers for Disease Control and Prevention, National Center for Injury Prevention and Control. March 2021.
[38] WMT_MDL_000042957, POM 1313.
[39] ROPP-0061 – Protocol for Dispensing Narcotic Drugs for Pain Treatment, CVS-MDLT1-000081566.
[40] ROPP-047561 - Federal Guidelines for Controlled Substances: CVS-DR22-000001039.
[41] 2011 – WAGMDL00008104/WAGMDL00767022; 2012 – WAGMDL00742666, WAGMDL00745753/66617 (DUR alert for drug cocktails).

As evidence of the fact that they were late at promulgating and implementing a system of red flags, Walgreens and Walmart entered into Memoranda of Understanding or Agreement with the DEA and DOJ arising from DEA enforcement actions based upon their failure to identify and resolve these red flags of diversion in 2009-2011. CVS developed its first guidelines to pharmacists regarding warning signs of diversion only after receiving a direct warning from the DEA around the same time, later resulting in the *Holiday* decision and suspension of CVS's license.

Evidence that the abuse of opioids was well known and should have been known by the Defendants extends beyond the reports issued by the CDC, the DEA, and other credible government sources. In the face of the overwhelming evidence concerning the abuse of prescription opioid medications, the defendants failed to address the presence of the opioid prescription epidemic in their pharmacies and the significance of red flag analysis as a critical component to prevent opioid drug diversion.

In *Jones Total Health Care Pharmacy, L.L.C., and SND Health Care, L.L.C.*; Decision and Order,[42] the DEA noted that an administrative law judge had "specifically rejected" the argument that a pharmacy owner, whose charged conduct occurred in the 2010-2012 time-frame, **"**was simply naïve or unaware of various indicia (otherwise known as red flags) that the prescriptions her pharmacy filled lacked a legitimate medical purpose as well as its contention that during the relevant time period," and credited testimony that, in "2010, Florida pharmacists were generally aware of various red flags of abuse and diversion." The decision also notes that, although an expert had "testified that the first reference to the term 'red flag' that she could find in DEA's public pronouncements was in the Holiday CVS decision," that was incorrect, as "the term appears in DEA administrative decisions involving practitioners including pharmacies" earlier than that, as well as "federal court decisions that predate 2010." *Id.* at Note 23 (citing *Paul J. Caragine*, 63 FR 51592, 51600 (1998); *Medicine Shoppe-Jonesborough*, 73 FR 364 (2008); *United Prescription Services, Inc.*, 72 FR 50397 (2007); *Medicine Shoppe- Jonesborough v. DEA*, 300 Fed. Appx. 409, 413 (6th Cir. 2008); *United States v. Alerre*, 430 F.3d 681, 686 (4th Cir. 2005); *United States v. Chin*, 795 F.2d 496, 502 (5th Cir. 1986).

The same agency decision notes that "[i]n any event, the term 'red flag' has been part of the lexicon for more than 200 years, and whether the Agency has used this term, or such terms as 'warning signs' or 'suspicious circumstances,' is of no consequence." *Id.* (explaining that "[w]hat matters is whether Respondent's pharmacists either knew or were willfully blind to the fact that the controlled substance prescriptions they dispensed lacked a legitimate medical purpose"). As a matter of pharmacy practice, it is my opinion that a pharmacy chain could and should have used the data available to them, including but not limited to their own dispensing data, to assist their pharmacist and pharmacies in detecting and addressing red flags for diversion. *See* Section D. above.

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[42] *Jones Total Health Care Pharmacy, LLC v. Drug Enf't Admin.*, 881 F.3d 823 (11th Cir. 2018), available at https://www.deadiversion.usdoj.gov/fed_regs/actions/2016/fr1110_3.htm.

What follows is a list and description of certain red flags of diversion and the number of times that each red flag appeared in Defendants dispensing data from their pharmacies in Lake and Trumbull counties.

Red Flags of diversion can generally be categorized Prescriber Red Flags, Patient Red Flags, Prescription Red Flags and Pharmacy Red flags.

Defendants in this action have produced dispensing data from the pharmacies they operated in Lake and Trumbull counties Ohio. A number of Red Flags can be identified using the dispensing data. I have relied upon SLCG and Craig McCann to review and calculate the number of prescriptions dispensed, the amount of dosage units dispensed, and the morphine milligram equivalents dispensed for each red flag by pharmacy chain that I have identified below. These summaries can be found in Dr. McCann's report as red flags 1-16 ("Red Flag Computations").

1. Patients traveling long distances to fill opioid prescriptions –

    a. Pharmacy Distance- Patient generally travels over 25 miles to pharmacy.
    b. Prescriber Distance- Patient generally travels over 25 miles to prescriber.

In the usual and customary practice of pharmacy, patients ordinarily frequent pharmacies that are convenient to their lifestyles. That convenience translates into using a pharmacy that is close to their residence or place of employment. Exceptions can occur when the individual's drug coverage under their insurance plan mandates certain pharmacies, the pharmacy that they frequent is out of a medication, or the patient is being treated by practitioners at a tertiary care facility that is highly specialized to provide services such areas as cardiac surgery, cancer treatment and management, burn treatment, plastic surgery, neurosurgery and other complicated treatments or procedures. From the data reviewed, these exceptions did not appear to be factors impacting the data. Further, according, to the CDC, nearly nine out of ten Americans live within five miles of a community pharmacy.[43] An earlier study stated that "more than 90% of Americans live within 2-miles to one of these pharmacies."[44] A patient that travels an inordinate distance (greater than 25 miles) to a particular pharmacy to obtain controlled substances is a recognized red flag that should be known to a pharmacist.[45] The use of 25 miles as a reference point is based upon standards used by states

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[43] CDC, Get to Know Your Pharmacist, https://www.cdc.gov/heartdisease/pharmacist.htm.

[44] Dima Qato, Shannon Zenk, Jocelyn Wilder, Rachel Harrington, Darrell Gaskin, & G. Caleb Alexander, *The availability of pharmacies in the United States: 2007–2015,* PLoS One 2017;12(8), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5559230/#pone.0183172.ref002.

[45] In the *Holiday CVS* administrative action, a patient travelling a long distance to fill prescriptions was noted as a red flag and "indicator of possible diversion"). In *Pharmacy Doctors Enterprises, Inc*., *v. Drug Enf't Admin.*, 789 Fed. Appx. 724, 730 (11th Cir. 2019), customers traveling "hundreds of miles

in establishing and permitting telepharmacies. In 2003, the North Dakota Board of Pharmacy was the first state to establish permanent rules allowing telepharmacy. North Dakota and other states utilized 25 miles or greater as one of the determinants for defining a telepharmacy in medically underserved remote rural communities.

The incidence of prescriptions for Pharmacy Distance - An opioid was dispensed to a patient who traveled more than 25 miles to visit the pharmacy. The distance here is calculated from the center of the patient's zip code to the center of the pharmacy's zip code:

Defendant	CVS	Walgreens	Walmart	HBC	[redacted]
Date Range	1/1/2006 - 11/29/2019	1/3/2006 - 1/3/2020	1/2/2006 - 4/25/2018	1/1/2006 - 12/3/2019	
Red Flag Script Count	7,210	7,414	2,409	2,889	

The incidence of prescriptions for Prescriber Distance - An opioid was dispensed to a patient who traveled more than 25 miles to visit their prescriber. The distance here is calculated from the center of the patient's zip code to the center of prescriber's zip code:

Defendant	CVS	Walgreens	Walmart	HBC	[redacted]
Date Range	1/1/2006 - 11/29/2019	1/3/2006 - 1/3/2020	1/2/2006 - 4/25/2018	1/1/2006 - 12/3/2019	
Red Flag Script Count	53,820	37,066	12,310	29,231	

Indeed, Defendants' own policies and internal documents, albeit promulgated after an unreasonable delay in time, recognize that an inappropriate distance traveled between a patient and a prescriber and a patient and a pharmacy is a red flag of diversion.

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roundtrip" was again noted as a red flag. Finally, in *East Main Street Pharmacy*, patients "driving long distances to have their prescriptions filled" was demarcated as a red flag and particularly, the "pattern of patients traveling long distances from the location of their home and physician is extremely unusual and very suspicious." *East Main Street Pharmacy,* Affirmance of Suspension Order, 75 FR 66149-01 (October 27, 2010) ("*East Main Street Pharmacy*").

Walmart: Prescriber or individual is "outside of the pharmacy's trade area."[46]

CVS: "[E]ither or both the patient and prescriber not being located within the store's geographic areas (in most cases)."[47]

Walgreens: "Unusual geographical distances between patient, pharmacist, and prescriber"[48]). "Individual resides outside of the trade area of your pharmacy, prescription is written by a prescriber located outside of the pharmacy's trade area."[49]

[redacted][50]

Giant Eagle: "Further than expected distances of the patient and/or medical provider from the pharmacy."[51]

Further, in 2015, a coalition of stakeholder organizations, including Defendants CVS, Rite Aid, and Walgreens, and the trade organization for the chain drug stores, the National Association of Chain Drug Stores ("NACDS"), among others, along with the NABP released a consensus document ("NABP Stakeholder Report") on the challenges and "red flag" warning signs related to prescribing and dispensing controlled substance prescriptions."[52] The NABP Stakeholder Report also recognized as a red flag patients "traveling unexplainable and/or unreasonably long distance to a physician office and/or the pharmacy" (long distance).[53]

Additionally, NACDS included as a red flag instances where "[p]atient travels long distance to physician and/or pharmacy."[54]

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[46] WMT_MDL_000042957 at 42958. (POM 1311 (2015)); *see also* WMT_MDL_000069117 (POM 1311 (2011)) ("the prescription was written by an out-of-state prescriber").
[47] CVS-DR22-000001039
[48] WAGMDL00093367 Good Faith Practices (Revised 08/01/98).
[49] WAGMDL00256710, April 2013 Presentation, Pharmacist GFD Review Coaching Opportunities.
[50] [redacted]
[51] HBC_MDL00191292, Giant Eagle, Pharmacy Controlled Substance Dispensing Guideline.
[52] WAGMDL00502238, Stakeholders' Challenges and Red Flag Warning Signs Related to Prescribing and Dispensing Controlled Substances.
[53] *Id.*; *see also* NABP_00022121, Stakeholders' Challenges and Red Flag Warning Signs Related to Prescribing and Dispensing Controlled Substances.
[54]WMT_MDL_000891159.

2. Doctor Shopping

Doctor shopping, as a red flag, includes when a patient presents a prescription for a controlled substance and may be obtaining the same or similar controlled substance from a different prescriber(s) and the patient does not make the prescriber aware of the other prescriber.[55] The red flag assists with the identification of individuals who are searching for a cooperative prescriber who will willingly prescribe the desired controlled substances.[56]

The data reveals as follows regarding patient was dispensed opioid prescriptions with overlapping days of supply that were written by two or more prescribers:

Defendant	CVS	Walgreens	Walmart	HBC	[redacted]
Date Range	1/1/2006 - 11/29/2019	1/3/2006 - 1/3/2020	1/2/2006 - 4/25/2018	1/1/2006 - 12/3/2019	
Red Flag Script Count	21,929	29,641	5,229	21,885	

3. Pharmacy Shopping

Pharmacy shopping occurs as a red flag when a patient travels to multiple pharmacies to fill controlled substances prescriptions with the intent moving from pharmacy to pharmacy in the hopes of getting multiple controlled substances without being detected. In the usual and customary practice of pharmacy, the overwhelming percentage of patients (>60%) use one pharmacy as their primary source of medications. Clinically, the overall health status appeared to be the worst for patients filling at multiple pharmacies concurrently and similarly, non-adherence higher.[57]

Patient was dispensed opioid prescriptions with overlapping days of supply at two or more pharmacies:

Defendant	CVS	Walgreens	Walmart	HBC	[redacted]

[55] Stakeholders' Challenges and Red Flag Warning Signs Related to Prescribing and Dispensing Controlled Substances, WAGMDL00502238; WMT_MDL_000891159.
[56] *Id.*
[57] Zachary Marcum, Julia Driessen, Carolyn Thorpe, Walid Gellad, & Julie Donohue, *Impact of Multiple Pharmacy Use on Medication Adherence and Drug-drug Interactions in Older Adults with Medicare Part D.*, J Am Geriatr Soc. 2014 Feb; 62(2): 244–252.

Date Range	1/1/2006 - 11/29/2019	1/3/2006 - 1/3/2020	1/2/2006 - 4/25/2018	1/1/2006 - 12/3/2019	[redacted]
Red Flag Script Count	10,682	20,385	0	6,221	

Defendants' policies and documents recognized, again long after the epidemic was in full swing, that doctor shopping and pharmacy shopping were red flags:

> Walmart: Patient red flags include: "evidence of "doctor shopping" and "pharmacy shopping" (often tied with traveling long distances)[58]
>
> CVS: "Doctor Shopping—Evidence of multiple doctors prescribing controlled prescriptions for customer…" [59] "Doctor shopping refers to the practice of an individual patient (who may or may not have legitimate medical issues) visiting multiple doctors in order to obtain multiple prescriptions for a controlled substance. The individual will typically have the multiple prescriptions filled at different pharmacies."[60]
>
> Walgreens: "evidence" of "doctor shopping" and "pharmacy shopping" are red flags of diversion.[61]
>
> [redacted]
>
> Giant Eagle: "[f]urther than expected distances of the patient and/or medical provider from the pharmacy"[62] and "doctor shopping" is a "drug diversion activity"[63] and "comparing the geographic location (zip code) of the patient to the location of the provider who wrote the prescription … [and] the location of the dispensing pharmacy… [can] identify possible 'doctor shopping schemes' or 'script mills'…." [64]

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[58] POM 1311, Practice Compliance, Proper Prescriber-Patient Relationship/Corresponding Responsibility, WMT_MDL_000042957.
[59] CVS-MDLT3-000006234.
[60] CVS-NYAG-000030739.
[61] WAGMDL00021306.
[62] HBC_MDL00191292.
[63] HBC_MDL00052112, Surescripts Presentation to Giant Eagle.
[64] HBC_MDL00043243.

NABP Stakeholder Document

The NABP Stakeholder Report: "Patient presents a prescription for controlled substance that the pharmacist knows, or reasonably believes, that another pharmacy refused to fill."[65]

4. Drug cocktails: "Holy Trinity" - An opioid, a benzodiazepine and a muscle relaxer were dispensed to a patient concurrently.

Combining drugs to achieve a desired clinical outcome, a cocktail, is an accepted means of therapy employed to treat patients diagnosed with complex conditions such as cancer or infection with the HIV virus. In these examples, the medical literature documents the effectiveness of the combinations and rationale for their use. Cocktails composed of drugs of abuse, such as opioids, lack any documented medical efficacy and conversely, are well-documented in the literature because of the dangers posed to patients, propensity for addiction, and the mimicking effects of illegal drugs such as heroin.

The Defendants' data included prescriptions issued and dispensed for drug cocktails, particularly cocktails referred to as "Trinities." Trinity is a broad term and can include different combinations of opioid/non-opioid prescriptions intended for abuse and to create a euphoric feeling similar to heroin and other illicit drugs.[66] The classic trinity or "Holy Trinity" consists of an opioid, a benzodiazepine, and a muscle-relaxer such as carisoprodol.[67]

When combined, the three drugs produce enhanced euphoric effects beyond the effect of the individual drugs. Alarmingly, the combination of opioids and benzodiazepine in this trinity combination also intensifies the risk of overdose and death. All of the trinity drug cocktail

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[65] Stakeholders' Challenges and Red Flag Warning Signs Related to Prescribing and Dispensing Controlled Substances, WAGMDL00502238.

[66] Complaint, *U.S. v. Walmart Inc.*, No. 11:20-cv-01744-CFC, p. 102 (D. Del. Dec. 22, 2020).

[67] The Holy Trinity drug cocktail has been described in DEA administrative decisions as early as 2008. *See Your Druggist Pharmacy*, 73 Fed. Reg. 75,774, 75,775 n.1 (DEA Dec. 2008) - "[w]hile carisoprodol [was] not controlled under Federal law, it is controlled under various state laws and is highly popular with drug abusers, especially when taken as part of a drug cocktail that includes an opiate and a benzodiazepine." In *U.S. v. Evans*, 892 F.3d 692, 706 (5th Cir. 2018), which arose out of charges based on conduct occurring between 2010 and 2012, it was noted that the combination of opioids, benzodiazepines, and a muscle relaxer such as carisoprodol is "a well-known and highly abused drug cocktail." This finding was also made in other actions including, but not limited to, *East Main Street Pharmacy* - "the combination of a benzodiazepine, a narcotic and carisoprodol is well known in the pharmacy profession as being used 'by patients abusing prescription drugs."; *Holiday CVS*, - citing drug cocktails issued by physician for oxycodone, benzodiazepines and carisoprodol and their abuse potential.

prescriptions dispensed by the Defendants presented significant red flags that a pharmacist in the usual and customary practice of pharmacy would have recognized. The red flags indicated that the prescriptions were not issued for a legitimate medical purpose or in the usual course of pharmacy practice. Supporting this determination is the finding that the Defendants filled a substantial number of drug cocktails (as described above) when the three drugs were filled either at the same time or with significant overlap to alert the pharmacist that the drugs would be taken together. Further, there were additional red flags present, including but not limited to, excessive quantities and the duration of therapy outside of recommended dosages and dosing to further concern and alert the pharmacist.

Patient was dispensed an opioid, a benzodiazepine and a muscle relaxer for overlapping days of supply:

Defendant	CVS	Walgreens	Walmart	HBC	[redacted]
Date Range	1/1/2006 - 11/29/2019	1/3/2006 - 1/3/2020	1/2/2006 - 4/25/2018	1/1/2006 - 12/3/2019	
Red Flag Script Count	22,885	32,412	7,735	21,386	

These concerns are heightened when the cocktail prescriptions were written by the same prescriber and filled by the pharmacy on the same day. Patient was dispensed an opioid, a benzodiazepine and a muscle relaxer on the same day and all the prescriptions were written by the same prescriber:

Defendant	CVS	Walgreens	Walmart	HBC	[redacted]
Date Range	1/1/2006 - 11/29/2019	1/3/2006 - 1/3/2020	1/2/2006 - 4/25/2018	1/1/2006 - 12/3/2019	
Red Flag Script Count	6,120	8,901	2,467	6,262	

5. Drug Cocktail: An opioid and benzodiazepine.

The medical literature has shown increased risk of respiratory depression when taking an opioid with a benzodiazepine since 2002.[68] Pharmacy practice has recognized drug combinations which include opioids and benzodiazepines as being generally known as being popular with drug abusers by at least 2005.[69] In 2015, 23 percent of people who died of an opioid overdose also tested positive for benzodiazepines.[70] A study of over 300,000 continuously insured patients receiving opioid prescriptions between 2001 and 2013, found that people concurrently using both drugs were at higher risk of visiting the emergency department or being admitted to a hospital for a drug-related emergency. More than 30 percent of overdoses involving opioids also involve benzodiazepines.[71] Other studies highlighted the dangers of co-prescribing opioids and benzodiazepines. A cohort study in North Carolina found that the overdose death rate among patients receiving both types of medications was 10 times higher than among those only receiving opioids.[72]

In the usual and customary practice of pharmacy, the combination of an opioid and benzodiazepine, both CNS depressants, would have alerted a pharmacist that the combination is dangerous and contraindicated because of the extenuated adverse effects of the drugs particularly sedation and suppression of breathing.[73] The suppression of breathing is the primary the cause of

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[68] John Caplehorn & Olaf Drummer, *Fatal methadone toxicity: signs and circumstances, and the role of benzodiazepines*, Aust N Z Public Health, 2002 Aug: 26(4): 358-362.

[69] *East Main Street Pharmacy*, 75 FR 66149, 66163 (October 27, 2010) (drug cocktails which include benzodiazepine, opioids, and muscle relaxers are widely known in pharmacy practice as being popular with drug abusers).

[70] Centers for Disease Control and Prevention (CDC), *Multiple Cause of Death, 1999-2015*, CDC WONDER Online (Apr. 4, 2017).

[71] Eric Sun, Anjali Dixit, Keith Humphreys, Beth Darnall, Laurence Baker & Sean Mackey, *Association between concurrent use of prescription opioids and benzodiazepines and overdose: retrospective analysis,* BMJ 2017;356: j760 (Jan. 30, 2017).

[72] Tae Woo Park, Richard Saitz, Dara Ganoczy, Mark Ilgen & Amy Bohnert, *Benzodiazepine prescribing patterns and deaths from drug overdose among US veterans receiving opioid analgesics: case-cohort study,* BMJ. 2015;350:h2698 (Apr. 15, 2015).

[73] John Caplehorn & Olaf Drummer, *Fatal methadone toxicity: signs and circumstances, and the role of benzodiazepines*, Aust N Z Public Health, 2002 Aug: 26(4): 358-362; Susanne Nielsen, Paul Dietze, Nicole Lee, Adrian Dunlop, & David Taylor, *Concurrent buprenorphine and benzodiazepines use and self-reported opioids toxicity in opioid substitution treatment,* Addiction 2007 Apr;102(4):616-22; Jermaine Jones, Shanthi Mogali, Sandra Comer, *Polydrug abuse: a review of opioid and benzodiazepine combination use,* Drug Alcohol Depend. 2012; 125(1-2):8-18.

overdose fatality.[74,75] The significance of the data reviewed is the actual dispensing of this combination of drugs of abuse and the number of times the combination was dispensed despite the findings and recommendations of medical experts and guidance from the DEA and other enforcement agencies.[76]

In a 2018 discussion on opioids, Dr. Patrice Harris, the former President of the American Medical Association, made clear that organizations position on patients who present with a prescription for both an opioid and a benzodiazepine stating, "that is a deadly, potentially, deadly combination." She went on to state that, at least in Georgia, "a lot of our overdose deaths were due to that combination."[77]

An opioid and a benzodiazepine were dispensed to a patient within 30 days of one another

Defendant	CVS	Walgreens	Walmart	HBC	[redacted]
Date Range	1/1/2006 - 11/29/2019	1/3/2006 - 1/3/2020	1/2/2006 - 4/25/2018	1/1/2006 - 12/3/2019	
Red Flag Script Count	84,777	122,923	26,427	89,220	

As with the Holy Trinity, even when Patient was dispensed an opioid and a benzodiazepine on the same day and all the prescriptions were written by the same prescriber.

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[74] Debra Dowell, Tamara Haegerich, Roger Chou, CDC *Guideline for Prescribing Opioids for Chronic Pain — United States, 2016,* Morbidity and Mortality Weekly Reports (Mar. 18, 2016).
[75] Food and Drug Administration, Safety Announcement, "FDA Warns about Serious Risks and Death When Combining Opioid Pain or Cough Medicines with Benzodiazepines; Requires Its Strongest Warning" (August 31, 2016).
[76] In *Pharmacy Doctors Enterprises d/b/a Zion Clinic Pharmacy*, the show cause order issued on February 23, 2015 listed red flags of diversion that Zion Clinic allegedly did not resolve prior to filling prescriptions. One of the red flags noted was the dispensing of an "opiate (hydromorphone) and benzodiazepine (alprazolam, clonazepam, diazepam, or lorazepam)." 83 Fed. Reg. 10,876 at 10,877. The decision noted further that this drug cocktail was popular with drug abusers. *Id*. Similarly, in *Jones Total Health Care Pharmacy, LLC v. DEA*, 881 F.3d 823 (11th Cir. 2018), red flags were defined and included drug cocktails "known for their abuse potential, such as oxycodone and a benzodiazepine." Accordingly, comparable determinations were made in *Holiday CVS* - the combination of an opioid and benzodiazepine like alprazolam "are commonly diverted to nonmedical use"; *East Main Street Pharmacy*.
[77] The Augusta Chronicle, "Dr. Patrice Harris Talks About Opioids," Aug. 12, 2018 https://www.youtube.com/watch?v=kbToYDmh16M.

Defendant	CVS	Walgreens	Walmart	HBC	[redacted]
Date Range	1/1/2006 - 11/29/2019	1/3/2006 - 1/3/2020	1/2/2006 - 4/25/2018	1/1/2006 - 12/3/2019	
Red Flag Script Count	52,525	82,719	18,646	61,969	

6. Drug Cocktail: Two short-acting.

Immediate-release opioids (in contrast to extended-release or long-acting opioids) release the drugs more quickly into the bloodstream and generally have a shorter analgesic effect than extended-release drugs. Studies in the clinical literature report that immediate-release or short acting opioids are more likely to lead to more abuse and aberrant behavior then long-acting opioids because of the pharmacokinetic and pharmacodynamic features of the immediate release products.[78] Pharmacists would recognize an obvious red flag when multiple prescriptions for immediate release opioids were presented at the same time or sufficiently close in time that the drugs would have overlapped.

The data detailed the repeated dispensing of prescriptions for multiple short acting opioids. Patient was dispensed two short acting opioid drugs on the same day:

Defendant	CVS	Walgreens	Walmart	HBC	[redacted]
Date Range	1/1/2006 - 11/29/2019	1/3/2006 - 1/3/2020	1/2/2006 - 4/25/2018	1/1/2006 - 12/3/2019	
Red Flag Script Count	5,158	9,119	1,981	4,768	

Defendants' policies, the Stakeholders report, and NACDS recognize dangerous drug combinations as red flags:

Walmart: POM 1311 (2015): "Prescriptions presented represent a 'cocktail' of commonly abused drugs or are presented in a combination that can cause medical complications."[79] Walmart only specified in 2017 that "cocktail" included "an opioid, a benzodiazepine, and a muscle relaxant . . . often referred to as the 'trinity' or 'holy trinity'" and added "[p]rescriptions for drugs with

[78] Laxmaiah Manchikanti, Rajeev Manchukonda, Vidyasagar Pampati, &Kim S Damron, *Evaluation of abuse of prescription and illicit drugs in chronic pain patients receiving short-acting (hydrocodone) or long-acting (methadone) opioids,* Pain Physician 2005;8(3):257-261.
[79] WMT_MDL_000042957.

opposite effects (e.g., stimulants and depressants)" and "prescription for drugs with similar effects (e.g., multiple long acting or multiple short acting opioids)" as additional red flags"

CVS: "Prescribes combinations the DEA has identified as having a high potential for abuse (e.g., oxycodone, alprazolam and carisoprodol)"[80]

Walgreens: "Prescriptions presented represent a cocktail of commonly abused drugs."[81] Also:

JUNE 7, 2012 "Controlled Substance Action Plan"

This says "Enhanced Drug Utilization Review"

"A DUR enhancement has been made to alert pharmacists to review a patient's profile and utilize Good Faith Dispensing procedures when dispensing select controlled substances.

- A Major DUR will flag when a patient has been prescribed medications, that in combination, have a high potential for abuse."
- The following message will appear to the pharmacist: "A strong association appears to exist between illicit use of Carisoprodol in combination with narcotic analgesics such as oxycodone and benzodiazepines such as alprazolam. . .."[82]

[redacted]

[80] ROPP 047561 – Federal Guidelines for Controlled Substances, CVS-DR22-000001011.
[81] April 2013 training guide WAGMDL00054501.
[82] WAGMDL00742642.
[83] [redacted].
[84] [redacted].

[redacted][85]

Giant Eagle: Giant Eagle's Controlled Substance Dispensing Guidelines (July 2013) lists (1) "prescriptions written together for: oxycodone/hydrocodone (opiate) + alprazolam (benzodiazepine) + carisoprodol (muscle relaxant as a potentiator)" and (2) "multiple prescriptions for the strongest formulations of hydrocodone and alprazolam."[86]

NABP Stakeholders Document: (1) "therapeutic duplication of two or more long-acting and/or two or more short-acting opiates (cocktails); and (2) patient presents prescriptions for highly abused "cocktails" (combination of opiate, benzodiazepine, and muscle relaxant) of controlled substance medications (cocktails).[87]

NACDS: includes "prescribing questionable 'cocktails' of commonly diverted drugs" and "prescribing combinations of drugs that can cause medical complications" as red flags.[88]

7. Excessive Dispensing

Pharmacies and pharmacists engaged in the usual and customary practice of pharmacy, at the time in question, were aware of, or should have known, that opioids prescribed at any dosage presented a risk to the patient. The risk to the patient should be evaluated in order to consider the individual patient benefits and risks. A retroactive 2017 study by the Centers for Disease Control (CDC) analyzed opioid prescribing at the national level from 2006-2015 and defined high dose prescribing rates to include prescriptions with daily dosage equal to or greater than 90 MME. Other studies examining the use of opioids and associated patient risks published in 2010 and 2011 demonstrated that the risk of overdose progressively increased at prescribed opioid dosages exceeding 20, 50,

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[85] [redacted].

[86] Giant Eagle, Pharmacy Controlled Substance Dispensing Guideline, HBC_MDL00191292.

[87] Stakeholders' Challenges and Red Flag Warning Signs Related to Prescribing and Dispensing Controlled Substances, NABP_00022121.

[88] NABP_00019878.

and 100 MME per day[89,90,91] and detected causal associations of prescribed opioids with overdose deaths.[92,93]

Additionally, a manuscript published in the Journal of the American Medical Association (JAMA) in 2016 discussing the CDC Guideline for Prescribing Opioids for Chronic Pain—United States, reported that "opioid-related overdose risk was dose-dependent, with higher opioid dosages associated with increased overdose risk. Compared with dosages of 1 to less than 20 MME per day, dosages of 50 to less than 100 MME per day were found to increase risks for opioid overdose by factors of 1.9 to 4.6, with absolute risk difference approximation of 0.15% for fatal overdose and 1.40% for any overdose. Dosages of 100 MME or more per day were found to increase risks for opioid overdose by factors of 2.0 to 8.9 relative to dosages of 1 to less than 20 MME per day, with absolute risk difference approximation 0.25% for fatal overdose and 4.04% for any overdose. Veteran Administration's patients with chronic pain who died of overdoses related to opioids were found to have been prescribed higher mean opioid dosages (98 MME/d) than controls (48 MME/d) and that above 200 MME per day, there was a continued increase in mortality rates."[94]

The presentation of a prescription for an excessive quantity of an opioid, or multiple opioids on the same day or within a period of time to cause overlap, was known or should have been known as a red flag requiring action by the pharmacist before dispensing the drug. That action would need to determine whether a legitimate patient-prescriber relationship existed validating the issuance of the prescription, the safety of the prescribed drug and dose(s) for the patient (particularly any dose exceeding recommended and safe dosages and MME values of greater than 90MME per day), and the possible existence of fraud or diversion.

Despite the obvious red flags, the Defendants repeatedly dispensed prescriptions that consisted of excessive quantities and dangerously high doses as noted below.

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[89] Kim Dunn, Kathleen Saunders, Carolyn Rutter, et al., *Opioid prescriptions for chronic pain and overdose: a cohort study*, Ann Intern Med 2010;152:85–92.
[90] Amy Bohnert, Marcia Valenstein, Matthew Bair, et al., *Association between opioid prescribing patterns and opioid overdose-related deaths,* JAMA 2011;305:1315–21.
[91] Tara Gomes; Muhammad M. Mamdani; Irfan A. Dhalla; et al., *Opioid dose and drug-related mortality in patients with nonmalignant pain,* Arch Intern Med 2011;171:686–91.
[92] Leonard J. Paulozzi, Christopher M. Jones, Karin A. Mack, Rose A. Rudd, *Vital signs: overdoses of prescription opioid pain relievers—United States, 1999–2008,* MMWR Morb Mortal Wkly Rep 2011;60:1487–92.
[93] Susan Okie, *A flood of opioids, a rising tide of deaths,* N Engl J Med 2010;363:1981–5.
[94] Deborah Dowell, Tamara M. Haegerich, & Roger Chou, CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016JAMA. 2016 April 19; 315(15): 1624–1645. doi:10.1001/jama.2016.1464.

Patient was dispensed an opioid prescription of over 200 MME per day before 2018 or over 50 MME per day after January 1, 2018.

Defendant	CVS	Walgreens	Walmart	HBC	[redacted]
Date Range	1/1/2006 - 11/29/2019	1/3/2006 - 1/3/2020	1/2/2006 - 4/25/2018	1/1/2006 - 12/3/2019	
Red Flag Script Count	5,372	15,135	1,012	4,148	

In addition, when the prescriptions are analyzed by examining where a patient was dispensed an opioid prescription of over 200 MME per day before 2018 or over 90 MME per day after January 1, 2018:

Defendant	CVS	Walgreens	Walmart	HBC	[redacted]
Date Range	1/1/2006 - 11/29/2019	1/3/2006 - 1/3/2020	1/2/2006 - 4/25/2018	1/1/2006 - 12/3/2019	
Red Flag Script Count	4,388	12,899	1,012	3,138	

Defendants' policies and the NABP Stakeholders report recognize excessive dispensing as a red flag:

Walmart: "prescription is for a large quantity (especially controlled substances)"/ "prescription is for a large number of a particular strength" (POM 1311 2009)[95], "prescription presented is for an unusually large quantity or high starting dose" (POM 1311 2015).[96]

CVS: "Appropriateness of Therapy: Overprescribing large doses of controlled substances to patients." (Note in 2012 they told pharmacists to contact prescriber if "concerns" about type and quantity "e.g., oxycodone 30 mg prescriptions for more than 180 dosage unit").[97]

Walgreens: "Prescriptions presented is for an unusually large quantity or high starting dose."[98] The Good Faith Dispensing program notes: "Increased frequency of prescriptions for same

[95] WMT_MDL_000069077.
[96] WMT_MDL_000042957.
[97] 2012, ROPP-0061 – Protocol for Dispensing Narcotic Drugs for Pain Treatment, CVS-MDLT1-000081566.
[98] WAGMDL00054510 (Note this is not in GFD, this is in training "Pharmacist GFD Review").

controlled drug: for quantities beyond those normally prescribed."[99] It also asks whether there is a trend, "unusual dosages, directions, or quantities beyond those normally prescribed."[100]

[redacted][101]

Giant Eagle: Giant Eagle's Controlled Substance Dispensing Guidelines (July 2013) lists "Large quantity of medication on a prescription from an emergency room."[102] NABP Stakeholders Report: "Patient presents prescriptions for large quantities or large number of prescriptions for controlled substances."

8. Pattern Prescribing

Pattern prescribing presents as a red flag when prescriptions are presented by multiple patients for the same medications, same strengths, approximately same quantities, and directions for use.[103] Prescribing the same medications to multiple patients erroneously supposes that the patients suffered from the same disease, exhibited the same symptoms, possessed identical patient factors (height, weight, metabolism rate, and allergies for example), took other medications that were identical, and suffered from the same adverse effects or contraindications. Clinically and in the usual and customary practice of pharmacy, this is not the case and would have served as a red flag regarding the prescribing of the practitioner and validity of the prescriptions.

> Same Day Prescribing – An opioid was dispensed to at least 4 different patients on the same day and the opioid prescriptions were for the same base drug, strength and dosage form and were written by the same prescriber:

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[99] WAGMDL00008106.
[100] *Id.*
[101] [redacted]
[102] HBC_MDL00191292.
[103] *Pharmacy Doctors Enterprises, Inc.*, 789 Fed. Appx. at 730 ("prescriptions written by the same doctor on the same day for the same strength of the same drug" is a red flag); East Main Street Pharmacy, supra, at 66157 ("[a]dditional red flags include '[m]aximum doses being seen for every single patient, lack of individuation of therapy, certain patterns from physicians of potential abuse of seeing the same types of controlled substances over, and over, and over, again.'"); *Holiday CVS*, supra, at 62318 ("prescriptions for the same drugs, the same quantities from the same doctor without any kind of variability or change considering the different patients that come into the pharmacy" is a red flag); *Id.* at 62333 (identifying "pattern prescribing" by a physician as an "unresolvable" red flag).

Defendant	CVS	Walgreens	Walmart	HBC	[redacted]
Date Range	1/1/2006 - 11/29/2019	1/3/2006 - 1/3/2020	1/2/2006 - 4/25/2018	1/1/2006 - 12/3/2019	
Red Flag Script Count	11,786	27,230	1,360	7,075	

Same Hour Prescribing – An opioid was dispensed to at least 3 different patients within an hour and the opioid prescriptions were for the same base drug, strength and dosage form and were written by the same prescriber:

Defendant	CVS	Walgreens	Walmart	HBC	[redacted]
Date Range	1/1/2006 - 11/29/2019	1/3/2006 - 1/3/2020	1/2/2006 - 4/25/2018	1/1/2006 - 12/3/2019	
Red Flag Script Count	7,845	10,193	2,343	19,624	

Defendants' policies recognize pattern prescribing as a red flag:

Walmart POM 1311 (2015): [redacted]

CVS: Prescribe the same medication in the same dosage amount to most or all of their patients"[105] and "Routinely prescribes the same combination of pain drugs for most or all of their patients."[106]

Walgreens: "Prescriber prescribes the same medication, with the same directions, for the same quantity for a large number of individuals."

[redacted]

Giant Eagle: "Lack of individualization of dosing."[107]

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[104] WMT_MDL_000042957.
[105] 2012, ROPP-0061 – Protocol for Dispensing Narcotic Drugs for Pain Treatment, CVS-DR22-000001062.
[106] *Id.*
[107] HBC MDL00191292.

9. Early fills/refills –
    a. An opioid prescription was refilled more than 5 days before the patient's previous prescription should have run out.

As trained pharmacists and licensed pharmacies were aware, when an individual requests that a controlled-substance prescription be filled significantly early, it raises a red flag regarding abuse or other diversion because it suggests that the individual is either taking a higher quantity than prescribed or diverting at least some of the medications to other individuals.

An opioid prescription was refilled more than 5 days before the patient's previous prescription should have run out:

Defendant	CVS	Walgreens	Walmart	HBC	[redacted]
Date Range	1/1/2006 - 11/29/2019	1/3/2006 - 1/3/2020	1/2/2006 - 4/25/2018	1/1/2006 - 12/3/2019	
Red Flag Script Count	2,508	2,224	544	3,450	

Defendants' policies and the Stakeholders report recognize early fills/refills as a red flag:

Walmart: Walmart had a policy, POM 1318 (2011),[108] [redacted]

CVS: "Early fill – Customer attempting refill early or consistently showing up at the first available moment when refill can be obtained under standard practices." (2014).[111]

[108] WMT_IN_AG_00000153.
[109] WMT_MDL_000042957.
[110] WMT_MDL_000067636.
[111] *See* March 2011, Course #800131, Biannual Compliance Training, CVS-NYAG-000030693.

Walgreens: "Consistent requests for early refills" or "Individual routinely attempts to obtain an early refill on controlled substances"[112] (As of 2013, used 8 days early for a 30-day supply, 90-days supply should be X days/percent (WAGMDL00437788)).

[redacted]

Giant Eagle: "Requests for early dispensing of refills."[113]

Stakeholders (includes CVS, Rite Aid, and Walgreens): "Pattern" of "frequently running out of medication for controlled substances early" and "controlled substance refill patterns being inconsistent with regular refill patterns for non-controlled chronic prescription medications."

10. Opioids Days' Supply

Opioids are inherently dangerous drugs that require strict adherence to the recommended doses and duration in order to avoid patient harm and reduce the risk of addiction and abuse. Prescription opioids and heroin are chemically similar and can produce a similar euphoric feeling or high. Prescription opioids used for pain relief should be prescribed and taken for a short time given their addictive properties and binding to and activation of[114] opioid receptors on cells located in many areas of the brain, spinal cord, and other organs in the body, especially those involved in feelings of pain and pleasure. When opioids attach to these receptors, they block pain signals sent from the brain to the body and release large amounts of dopamine throughout the body. This release can strongly reinforce the act of taking the drug, making the user want to repeat the experience. A patient prescribed opioids for longer than six months is not generally accepted medical treatment and is a red flag of diversion.

A patient was dispensed more than 210 "days of supply" of all opioids combined in a 6-month period:

Defendant	CVS	Walgreens	Walmart	HBC	[redacted]
Date Range	1/1/2006 - 11/29/2019	1/3/2006 - 1/3/2020	1/2/2006 - 4/25/2018	1/1/2006 - 12/3/2019	
Red Flag Script Count	45,571	71,048	12,094	38,025	

[112] 6/2011 Controlled Substance Prescriptions and GFD, WAGMDL00054509.
[113] HBC MDL00191292.
[114] National Institute of Drug Abuse. Prescription Opioid Drug Facts, May 2020.

11. Payment for an opioid by cash[115,116,117]

Paying cash for a prescription is a red flag of diversion. Oftentimes people who are paying cash for opioids are engaged in diversion and seek to obfuscate the purchase of controlled substances from review by payors and insurance companies. The likelihood of diversion increases in circumstances in which the patient pays for an opioid prescription with cash when they otherwise have insurance. The various programs that cover the cost of prescription medications afford little need to pay cash for prescriptions that would likely be covered by insurance thus avoiding out-of-pocket expenses for the individual.[118, 119]

A patient was dispensed an opioid and paid cash:

Defendant	CVS	Walgreens	Walmart	HBC	[redacted]
Date Range	1/1/2006 - 11/29/2019	1/3/2006 - 1/3/2020	1/2/2006 - 4/25/2018	1/1/2006 - 12/3/2019	
Red Flag Script Count	12,043	8,772	6,852	5,692	

Defendants' policies and the Stakeholders report recognizes cash payments as a red flag:

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[115] Federal Register / Vol. 83, No. 49 / Tuesday, March 13, 2018 / Notices.
[116] Federal Register / Vol. 81, No. 218 / Thursday, November 10, 2016 / Notices.
[117] Federal Register / Vol. 75, No. 207 / Wednesday, October 27, 2010 / Notices.
[118] Federal Register / Vol. 81, No. 218 / Thursday, November 10, 2016 / Notices.
[119] *Jones Total Health Care Pharmacy, LLC*, 881 F.3d at 828 ("cash purchases" of prescriptions is a red flag); *Pharmacy Doctors Enterprises, Inc.*, 789 Fed. Appx. at 730 (cash payments for prescriptions is a red flag); *Holiday CVS, supra*, at 62318, fn. 9 (cash payments for prescriptions is a red flag); 62326 ("large quantities of people paying cash" is a red flag), 62331 ("patients between the ages of 25 and 40 with cash" is a red flag), 62332 ("According to [Dr.] Doering [DEA expert], 'typically, people who may be diverting or otherwise misusing their drugs will pay cash.'"); *East Main Street Pharmacy, supra*, at 66150 (high percentage of cash payments compared to national average is a red flag); *id.*66158 (according to Dr. Sullivan, the DEA's testifying expert, this "is an obvious example of a pharmacy profiting from drugs that are most likely being abused or diverted for sale on the street' and that '[a]ny reasonable pharmacist knows that a patient that wants to pay cash for a large quantity of controlled substances is immediately suspect'").

[redacted]

CVS: "Cash – Cash payment for prescriptions, particularly if RxConnect indicates the patient has insurance." In 2011, 6.2.11 Identifying Forged or Altered Prescriptions. "Patient asks to pay cash for prescription."[121]

Walgreens: "Individual pays cash, or insists paying cash for controlled substances even though insurance is on file." "Does the patient request to pay by cash or by using a cash discount card (in a possible attempt to circumvent third party billing restrictions)"[122]

[redacted][23]

Giant Eagle: "Cash transactions on controls."[124]

NABP Stakeholders Document: "Requesting to pay cash for a controlled substance prescription, when it has been documented that he/she has insurance that would normally cover the prescription (cash)."

NACDS – "Patient pays with cash," citing *Holiday and East Main*, in which nearly 87% of a physician's patients "paid case for their prescriptions," a "red flag as '[a]ny reasonable pharmacist knows that a patient that wants to pay cash for a large quantity of controlled substances is immediately suspect.' *East Main*, 75 FR at 66164."[125]

Summary of Red Flags

The number of red flags identified in Defendants' dispensing data is indicative of a pattern of diversion in Lake and Trumbull counties. Roughly 19.4% of all prescriptions dispensed by the Pharmacy Defendants in Lake and Trumbull counties contained red flags indicative of diversion.[126]

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[120] WMT_MDL_000042957.
[121] ROPP-00059, CVS-MDLT1-000081559.
[122] GFD, WAGMDL00742666 at 742668.
[123] [redacted]
[124] HBC_MDL00191292.
[125] WMT_MDL_000891159.
[126] The flagged prescriptions were limited pursuant to the Court's May 10, 2021 order, Doc. #3726 to the prescriptions flagged by the universe of 884,166 prescriptions previously disclosed by Plaintiffs in their June 2020 Response to Interrogatories referred to as the "Combination Red Flagged Prescriptions." 19.4% is the percentage of red flag prescriptions identified from the total universe of all opioid,

Every red flag must be resolved before each prescription for a controlled substance is dispensed. The volume of red flagged prescriptions dispensed in these counties is unreasonable. Opioids are extremely addictive and highly subject to abuse as a result, all red flags are concerning. One would expect given the dangerous nature of these drugs and the presentation of well-known red flags that only a small percentage of prescriptions would be dispensed with unresolved or unresolvable red flags.

Red flags need not always be specific to the prescription being presented. A pharmacy should also be reviewing its dispensing data to take into consideration the totality of the circumstances, including the practitioner's prescribing patterns across different patients, e.g., large quantities, high-risk combinations, and similar diagnosis codes. That "totality of responsibility" requires the pharmacy or DEA registrant corporation to monitor the overall controlled substance volume and pertinent dispensing data. *See e.g.*, *United States v. Lawson*, 682 F.2d at 483 ("Lawson willingly ignored every signal that he should question the volume of controlled drugs being dispensed from his pharmacies.").[127] When a prescription contains a red flag that is not resolved, each subsequent prescription for that patient or prescriber is subject to flagging until all prior flags have been investigated and resolved.

In situations where diversion is suspected, the pharmacist and the pharmacy have a responsibility to report this suspicion to the appropriate regulatory and law enforcement authorities and document the facts of the situation and actions taken and refuse to fill the prescription.

The Defendants all participated in identifying and memorializing the following additional red flags of diversion:

- Physician writes large number or percentage of prescriptions for controlled substances.
- Recurring pattern of prescribing the same controlled substances to multiple patients which suggests the physician is operating a pill mill.
- Physician engages in the unauthorized practice of medicine.
- Physician no longer holds a DEA license.
- Pharmacy and/or pharmacist has excessive volume and rate of growth of dispensing controlled substances.
- Pharmacy and/or pharmacist dispensing data shows early fills "weeks early" on several occasions.

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benzodiazepine, and muscle relaxer prescriptions in the dispensing data produced by the Pharmacy Defendants in Lake and Trumbull counties, which totaled 4,556,574 per Dr. McCann.

[127] *See also* Deposition of former DEA diversion investigator Demetra Ashley, Ashley Dep. 132-134, stating that Chain Pharmacies could do the same red flag searches of their own computerized databases, and that it would be "reasonable" to expect pharmacies to access those databases to look for red flags, especially in the midst of a raging epidemic.

2. Additional Red Flags of Diversion

There are red flags of diversion that a dispensing operating system could not detect. Thus, it is critical that all pharmacy personnel be trained to identify and address these indicators of potential diversion. One category of these flags is suspicious behavior of the patient. Pharmacies should have appropriate training materials and controls to assist pharmacists and technicians in the identification of such behaviors. When the customer drops off a prescription at the pharmacy, observations of the patients' behavior should be made as part of the required validation of the prescription. Indicators of possible signs of diversion, or suspicious behavior include, stumbling while walking, slurred speech, appearance of intoxication, or of customers coming and appearing like they may not need the medication" or appearing like they may be high" *Holiday CVS, L.L.C., d/b/a CVS/ Pharmacy Nos. 219 and 5195*; Decision and Order, 77 Fed. Reg., No. 198 (2012), at 62326. Suspicious behavior that may indicate signs of diversion also include customers arriving in groups to get narcotic prescriptions filled. Multiple out-of-area patients from the same town or area is also a sign of diversion. *Id*. at 62319, 62331. Customers requesting their prescriptions by the brand name, by descriptions, or by street slang can also be a sign of diversion. For example, the terms "the M's", "the Blues," or "Mallinckrodt Blues" are common terms which are red flags and may be a sign of diversion. *Id.* at 62321, 62344.[128]

The Defendants also participated in identifying and memorializing the following additional red flags of diversion:

- Pharmacy and/or pharmacist fails to question and counsel patients regarding controlled substances.
- Pharmacy and/or pharmacist fails to contact other pharmacies with concerns.
- Pharmacy and/or pharmacist fails to follow documentation requirements.
- Pharmacy and/or pharmacist failure to follow "specific guidance" provided by DEA.
- "Coordination and referrals between pharmacist and physician."[129]

3. Multiple Red Flags

As each red flag is a potential indication of diversion, it is axiomatic that when a prescription is presented with multiple red flags the likelihood of diversion increases greatly. There are countless

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[128] For example, Giant Eagle's Controlled Substance Dispensing Guideline included "[p]atients requesting a medication by "street name" or insisting on brand" as one of several "other flags" HBC_MDL00191292.

[129] WMT_MDL_000891159.

combinations of red flags that could exist with a single prescription. In each instance, every red flag must be resolved before the prescription is filled. Many DEA cases describe various combinations of red flags. For example, the confluence of out of state patients on a single day receiving the same medications, in the same quantities, from the same prescriber, would be considered a combination of red flags that would each need to be resolved before filling a prescription. *Holiday CVS, L.L.C., d/b/a CVS/ Pharmacy Nos. 219 and 5195*; Decision and Order, 77 Fed. Reg., No. 198 (2012), at 62333. Similarly, the combination of flags of cash-discount method of payments, out of state or out of area patients, and the distance between the patients' home addresses and the prescriber would also demonstrate a combination of red flags to be resolved. *Id.* at 92333.

Each of the Pharmacy defendants should have had systems and programs in place to detect, report and store this information in a format that could be easily retrieved and reviewed by corporate headquarters and its pharmacists. If the information were stored in this format, it could have been used to identify patients and potentially their prescribers engaged in diversion.

The Combination Red Flagged Prescriptions includes 690,028 opioid prescriptions, out of a total of 884,166 prescriptions. Of those, there are 454,707 opioid prescriptions (or 65.90% of opioid prescription) that triggered 2 or more of the 16 red flag computations.[130]

F. Growth of Dispensed Opioids

Pharmacies are also in a unique position to monitor the volume of opioids being dispensed in their pharmacies relative to the size of the communities they serve. It has long been recognized that as to the supply of opioids increases, so does the incidence of over-dose and death. As a result, pharmacies should have been monitoring and investigating instances in which the number of opioids ordered and dispensed exceeded the legitimate medical needs for the communities they served. According to SLCG's calculation of the ARCOS data, between 2006 and 2014, chain pharmacy defendants in Lake County received 1.6 billion MME of opioids and chain pharmacy defendants in Trumbull County received 2.6 billion MME of opioids. Given Lake County's average 229,550 population, chain pharmacy defendants received enough opioids for every resident in the county to consume 794 MME every year from 2006 to 2014. Given Trumbull County's average 210,118 population, chain pharmacy defendants received enough opioids for every resident in the county to consume 1,349 MME every year from 2006 to 2014. The Ohio

[130] Expert Report of Dr. Craig McCann at Exhibit 14C.

Board of Pharmacy developed a presentation which described Ohio death rates from unintentional drug overdose, the impact of those overdose deaths and person and prescription analgesic doses per capita.[131]

The Chain Pharmacies were also in a position to monitor the prescribing habits for the practitioners whose prescriptions were dispensed from their pharmacies and identify high prescribers of opioids. The pharmacies should have gathered this information and shared it with its pharmacy staff in order that they could be on alert for prescriptions from these prescribers.

G. Notice to Chain Pharmacy Defendants from DEA Investigations and Suspensions

From their own past experience, and publicity surrounding other enforcement actions, the large chain pharmacy companies knew that if they, and their pharmacists, failed to comply with their legal obligations when dispensing controlled substances, they could face an enforcement action. Through these actions Defendants were given specific and detailed warnings from the DEA of the red flags and risks of diversion.

CVS has faced repeated enforcement actions, ranging from an action concerning conduct dating back to 2006 to more recently a settlement reached in 2019, with other enforcement actions occurring in the interim. The misconduct underlying the earliest enforcement action against CVS of which I am aware, which concerned CVS pharmacies in Oklahoma and was resolved through settlement in 2013, involved the filling of invalid "prescriptions" and/or failure to control against diversion, including with respect to the most basic steps such as ensuring a current, valid DEA number.

The DEA issued Orders to Show Cause against both Walgreens and Walmart in 2009. Both were initiated in relation to specific stores but resulted in Walgreens and Walmart each entering into separate Memoranda of Agreement ("MOAs") in 2011 that required nationwide reforms to their pharmacy policies, procedures, and programs. Walgreens agreed in its April 2011 MOA to "maintain a compliance program to detect and prevent diversion of controlled substances" as required under federal law." In that MOA, Walgreens expressly agreed that the program would include training and "procedures to identify the common signs associated with the diversion of controlled substances."

Walmart similarly agreed in 2011 to adopt a national compliance program intended to ensure that it fulfilled its legal obligations when filling controlled-substance prescriptions. In the MOA, Walmart committed to, among other things, "maintain a compliance program, updated as

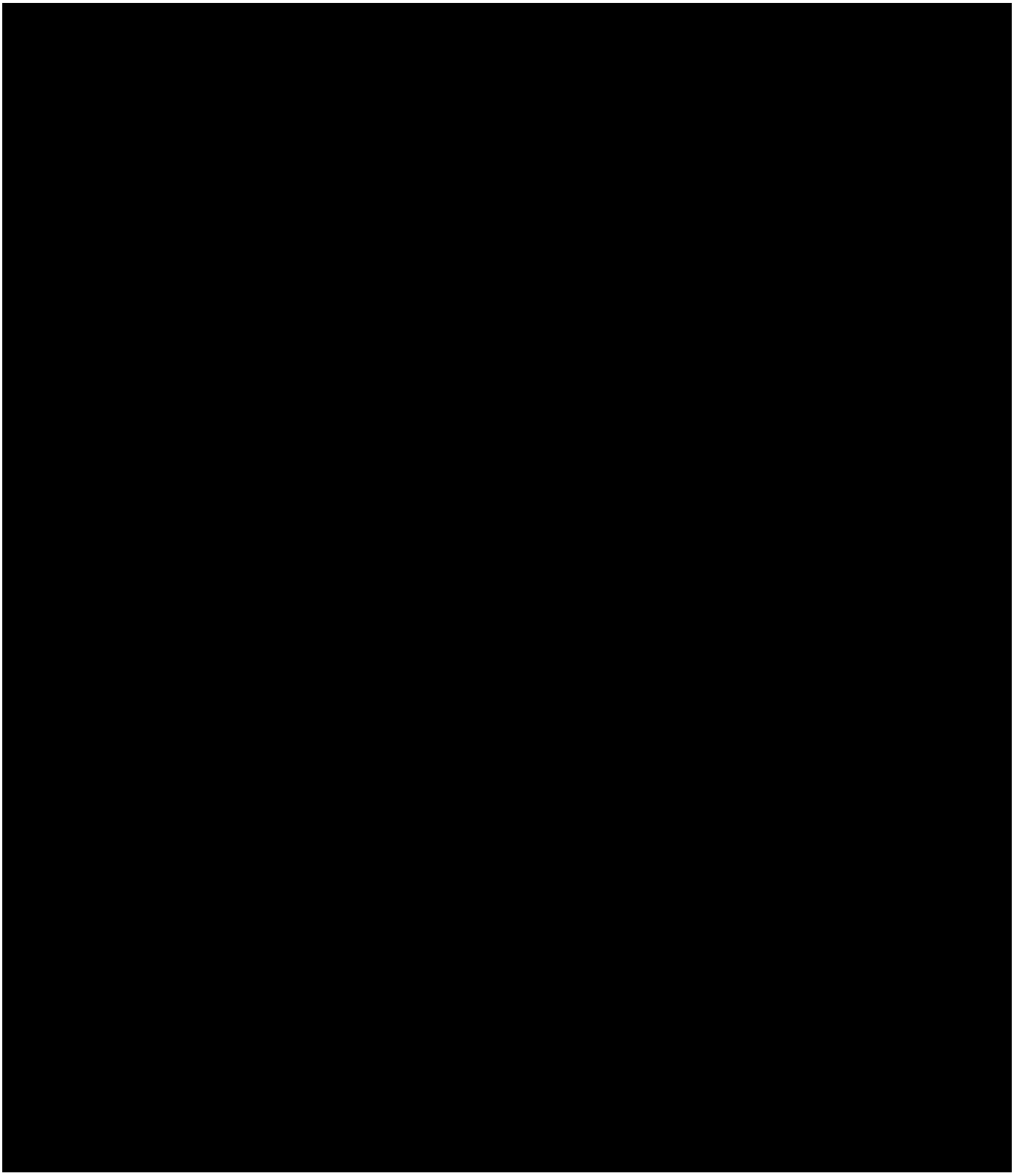
[131] BOP_MDL026939 – BOP_MDL027054.

necessary, designed to detect and prevent diversion of controlled substances as required by the Controlled Substances Act"; create a process that would ensure that its pharmacists were identifying common signs of diversion. Specifically, the MOA required that Walmart's compliance program would include procedures to ensure that pharmacists identified red flags to include procedures to identify the common signs associated with the diversion of controlled substances including but not limited to, doctor-shopping, requests for early refills, altered or forged prescriptions, prescriptions written by doctors not licensed to practice medicine in the jurisdiction where the patient is located, and prescriptions written for other than a legitimate medical purpose by an individual acting outside the usual course of his professional practice. It also agreed that if one of its pharmacists did conclude that a prescription was not issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice, was forged, or had been altered, and refused to fill that prescription, Walmart would notify the local DEA field office within seven business days of the refusal to fill. Walmart also specifically agreed to collect reports from its pharmacists when those pharmacists determined that controlled substance prescriptions were invalid and refused to fill them. The MOA was in effect from March 2011 through March 2015.

Both Walmart and Walgreens would face further enforcement action. This included a 2012 Order to Show Cause against Walgreens involving its Florida pharmacies, which again uncovered conduct implicating more widespread failures at a corporate level, not limited to stores in Florida. The 2012 Show Cause Order specifically addressed the 2-Drug Combination red flag discussed above, noting that: Walgreens pharmacy filled prescriptions for individuals presenting prescriptions for combinations of controlled substances known to be highly abused, such as oxycodone and benzodiazepines.[132] In 2015, Walmart settled claims that its pharmacists at a store in Rhode Island filled obviously forged controlled substance prescriptions.[133] In December of 2020, the U.S. Department of Justice ("DOJ") filed a lawsuit against Walmart alleging nationwide dispensing failures.

[redacted]

[132] 2012 Orders to Show Cause issued to Walgreens (WAGMDL00387708).
[133] WMT_MDL_000043497.
[134] [redacted]



[redacted]

Meanwhile, Giant Eagle's lack of supervision at a Chardon, Ohio store resulted in an Ohio Board of Pharmacy finding concerning its failure to deter or detect theft, referencing the period "from May 1, 2009 through January 21, 2011."[140]

The record of these actions highlights not only admonitions about the pharmacies' obligations, but the importance of these requirements. A Declaration submitted by then Deputy Assistant Administrator for DEA's Office of Diversion Control Joseph Rannazzisi, in *Holiday CVS, L.L.C., v. Holder*, Civ. No. 1:12-cv-191 (D. D.C Fed. 24, 2012), explained: "When registrants at every level—practitioners, pharmacies and distributors—fail to fulfill their obligations," the CSA's "necessary checks and balances collapse." *Id.* at ¶ 10. And "[b]ecause pharmacies are the entity providing the controlled substances to the end user, they are often the last major line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market." *Id.* (explaining that "[i]t is, therefore, incumbent on pharmacies to ensure that controlled substances are only dispensed pursuant to valid prescriptions issued for legitimate medical purposes in the usual course of professional practice"). The Declaration also notes, for example, that Florida's State Health Officer and Surgeon General in July 2010 issued a "statewide public health emergency declaration in response to the ongoing problem of prescription drug abuse and diversion in Florida"—a problem whose impact was felt well outside the state, as oxycodone and other controlled substances such as alprazolam from Florida was being "illegally redistributed in states along the entire east coast and Midwest." *Id.* at ¶¶ 15, 20.

Before taking action against CVS in 2012, DEA hosted a December 8, 2010, meeting attended by CVS' Head of Pharmacy Professional Services, Papatya Tankut and the CVS district supervisor. At that time, the Declaration explains, CVS's counsel acknowledged "that CVS was aware of the pill mill and/or pain clinic situation and the diversion of controlled substances, primarily oxycodone, in Florida." *Id.* at ¶ 27. CVS also acknowledge receipt of an October 2010 plea from a local sheriff "to work with law enforcement and closely scrutinize the prescriptions they receive." *Id.* at ¶ 29.

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138 [redacted]

139 [redacted]

140 OBPM_MDL_000000063.

CVS was advised by the DEA:

> that the diversion of oxycodone, primarily originating from purported pain clinics, involves fraudulent prescriptions, doctor shoppers, and unethical doctors. CVS was further advised of the typical "red flags" associated with the diversion of controlled substances that a pharmacy should be familiar with in order to carry out its corresponding responsibility to ensure that the controlled substances are dispensed for a legitimate medical purpose. Some of the "red flags" discussed included: (a) many customers receiving the same combination of prescriptions *(i.e.,* oxycodone and alprazolam); (b) many customers receiving the same strength of controlled substances *(i.e.,* 30 milligrams of oxycodone with 15 milligrams of oxycodone and 2 milligrams of alprazolam); (c) many customers paying cash for their prescriptions; (d) many customers with the same diagnosis codes written on their prescriptions (L *e.,* back pain, lower lumbar, neck pain, or knee pain); and (e) individuals driving long distances to visit physicians and/or to fill prescriptions.

Id. at ¶ 28.

During the December 2010 meeting, CVS also acknowledged awareness of an increase in oxycodone prescriptions at Florida CVS stores. *Id.* at ¶ 29. DEA discussed "a summary from DEA's Automation of Reports and Consolidated Orders System (ARCOS) records" showing that the increase at one store, which was already ordering "more than four times the amount of oxycodone a typical pharmacy orders in one year" in 2006, was "huge," with a more recent 10-month history showing it ordered "more than thirty times what a typical pharmacy ordered in one. *Id.* at ¶ 31. During the same meeting, DEA also made clear that CVS's instruction to its pharmacists to call the prescriber "representatives that verifying that the prescription was written by a physician was not the same as making an independent determination that the prescription was written for a legitimate medical purpose in the usual course of professional practice. *Id.* at ¶ 30.

"On August 12, 2011, DEA hosted a second meeting with CVS at the DEA Weston Resident Office," attended by "24 supervisors/managers from various South Florida CVS pharmacies." *Id.* at ¶ 33. "The presentation included," among other information, "statistical information" that "showed drastic increases in prescription drug overdose deaths." *Id.* at ¶ 34. At that meeting, the DEA again reminded CVS of corresponding responsibility under the CSA and:

> the typical "red flags" associated with the diversion of controlled substances that a pharmacy should be familiar with in order to carry out its corresponding responsibility to ensure that the controlled substances are dispensed for a legitimate medical purpose. Some of the "red flags" discussed included: (a) many customers receiving the same combination of prescriptions; (b) many customers receiving the same strength of controlled substances; (c) many customers paying cash for their prescriptions; (d) many customers with the same diagnosis codes written on their prescriptions; (e) individuals driving long distances to visit physicians and/or to fill prescriptions; (f) customers coming into the pharmacy in groups, each with the same prescriptions

> issued by the same physician; and (g) customers with prescriptions for controlled substances written by physicians not associated with pain management (i.e., pediatricians, gynecologists, ophthalmologists, etc.).

Id. at ¶ ¶ 35-36. After the DEA executed Administrative Inspection Warrants at two Florida CVS stores discussed in the meetings, interviews with CVS pharmacists revealed that no one spoke with the pharmacist in charge of one store about the staggering amounts of oxycodone discussed in CVS's December 2010 meeting with the DEA and the pharmacist was unfamiliar with multiple red flags. *Id.* at ¶ 41.a. Other employees believed it was not their job to "police the patients" and described measures the stores had implemented as they filled prescriptions that were "probably were not legitimate." *Id.* at ¶ 41. These included daily limits designed to "ensure that the pharmacy had enough oxycodone 30mg to fill the prescriptions for 'real pain patients'" and the job duty of one employee who acted "as the "bouncer" for a CVS store. *Id.* The CVS employees "consistently ignored the red flags of controlled substance diversion," and, until CVS faced heightened DEA scrutiny, filling prescriptions for more than twenty prescribers who later faced enforcement action themselves, none of whom were located in the same city as the stores, and most of whom were some distance away. *Id.* at ¶¶ 43 & 54-55.

As a result of these DEA enforcement actions related to Defendants and other pharmacies for failures to maintain effective controls to guard against diversion in pharmacy practice, as well as warning from the DEA given to the Defendants, one would expect the number of drugs dispensed in the face of red flags to have significantly declined meaningfully over time. However, a review of annualized instances of red flags request calculated by Dr. McCann did not reveal significant reduction in the amount of prescription filled in the face of the red flags over time.

H. Investigate, Resolve and Document Resolution of Red Flags

Consistent with best pharmacy practice and the warnings and agreements entered into with the DEA, Defendants' own policies recognize and require that when a controlled substance prescription has multiple red flags, each flag must be resolved before that prescription is dispensed. The pharmacist must also document how that red flag was resolved. Documentation is critical for several reasons. It offers an explanation as to how the pharmacist resolved any red flags to allow for the dispensing of the prescription or why the pharmacist refused to fill the prescription and the steps taken afterwards. Documentation also affords the pharmacy the opportunity to review, audit and investigate whether red flags are being identified and appropriately resolved, and it assists the DEA in the event there is a need to conduct an investigation related to diversion.[141]

[141] John Aivazis Dep. 316:12 – 317:1, May 13, 2021.

Recordkeeping is one of the Controlled Substance Act's primary means for preventing the diversion of controlled substances. Grider Drug 1 & Grider Drug 2, 77 FR 44,070, 44,100 (citing Paul H. Volkman, 73 FR 30,630, 30,644 (2008)). Under the Act, "every registrant . . . dispensing a controlled substance or substances shall maintain, on a current basis, a complete and accurate record of each such substance . . . received, sold, delivered, or otherwise disposed of by him." 21 USC 827(a). DEA enforcement decisions have explained that "a registrant's accurate and diligent adherence to [its recordkeeping] obligations is absolutely essential to protect against the diversion of controlled substances." Volkman, 73 F.R. at 30,644. The DEA pharmacy handbook further emphasizes that complete and accurate recordkeeping "provide[s] accountability of all controlled substances from the manufacturing process through the dispensing pharmacy and to the ultimate user." (DEA Pharmacy Handbook, 2020 Edition, p. 35.)

Defendants' data did not contain complete and accurate dispensing information related to, among other information, prescriber DEA numbers, prescriber names, prescriber NPI numbers, prescribers' addresses information, prescriber specialty information, prescription quantity, or dispensing pharmacist. These data deficiencies preclude defendants from maintaining effective controls to prevent abuse and diversion.

As calculated by Dr. McCann, of the 3,342,140 opioid prescriptions dispensed in Lake and Trumbull Counties by defendants, approximately 4% or 133,270 of the controlled substance prescriptions in the dispensing data did not include the prescriber's DEA number. Additionally, some DEA numbers were inaccurate and did not follow DEA number conventions (i.e., "AU000000" [Patient ID=8809772: Fill Date=2010-08-25]). Similarly, about 9% of DEA numbers were associated with multiple prescribers. DEA numbers are a requirement for filling prescriptions for controlled substances, and accurate DEA numbers are necessary to ensure the prescriber maintains a license to prescribe controlled substances.

For some prescriptions, prescribers' addresses were missing, unknown, or fraudulent (i.e., "123 SOMEWHERE, IDONTKNOW, OH" [Patient ID=33879a4a5310aaf145edd6c6ee1f31b8: Fill Date=2007-05-10]) when defendants choose to produce the information.[1] Additionally, some pharmacies choose to include prescriber-related notes in the address fields (i.e., "do not use has been arrested" [Patient ID=5100370097: Fill Date=2009-04-28]). Across all defendants, inconsistent spelling and naming formats resulted in prescribers existing in defendants' dispensing records under multiple names. As an example, the prescriber's last name of "Amir," "Amirthalingam," and "Amirthalingham" are associated with DEA number AA140223. About one-third of prescriptions lacked prescriber specialty information when defendants choose to provide that information. Also, about 10% of opioid prescriptions did not reflect the type of

[1] The Court did not require defendants to produce pharmacy, prescriber or patient address information beyond zip code. Where defendants choose to provide additional address information, that information was evaluated for accuracy and completeness.

payment used by the patient to purchase the prescription. And lastly, a substantial number of prescriptions, or approximately 21%, lacked the dispensing pharmacist's name or identifier.

These data deficiencies underscore the defendant's inadequate recordkeeping and failure to maintain effective abuse and diversion monitoring programs.

The need to monitor and document steps taken with respect to accessing of the PDMP is also important. Many of the Defendants were very slow to require that a search of the PDMP be conducted for each opioid and cocktail prescription. The Defendants left this to the discretion of the pharmacist instead of requiring that the PDMP be searched prior to dispensing. In addition, there was not a system or program to track and document when the PDMP was searched and the results of that search.

While the Defendants' policies eventually largely contained these best practices, they were slow to implement such requirements – most after 2012 and 2013; Walmart not until 2015—and when they did, the policies were often inadequate.

Walmart

Until 2015, [redacted] Walmart provided inadequate guidance to pharmacists on how to respond to prescriptions that raised one or more red flags. [redacted]

[redacted]

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[142] For early refills, POM 1318 (2011) required the pharmacist to evaluate "the circumstances for the request and the patient's medication and previous refill history." Furthermore, POM 1318 (2011) stated that "[i]f the pharmacist overrides the warning and allows the refill to go through, whether the approval was obtained from the prescriber or in the exercise of the pharmacist's professional judgment, then Walmart, through the Connexus system, requires the pharmacist to document the reason for the override." The policy emphasized that "[i]t is important that pharmacists thoroughly and accurately document any details associated with their decisions to override early refill warnings, including any discussions with or approval from the prescriber."

[143] WMT_MDL_000154713.

[144] WMT_MDL_000180253 (July 2015 POM 1311).

[145] WMT_MDL_000180253 (July 2015 POM 1311).

[redacted]

[redacted][146]

Even today, as Walmart's director of global compliance recognized in a draft presentation from December 2020, [redacted]

CVS

On December 10, 2010, two days after meeting with Joe Rannizzisi who warned CVS of the red flags of diversion, CVS issued a guideline entitled "Dispensing Guidelines for Pain Management." The DEA determined that CVS policies were not effective in preventing CVS pharmacists from filling prescriptions in the face of red flags of diversion. DEA found that interviews conducted with employees of CVS 219 and 5195 showed that the pharmacies were dispensing controlled substances even with the existence of the 'warning signs'"[152] identified in CVS guidelines. The guidelines described certain warning signs, but did not describe those signs as red flags and did not instruct pharmacists that each red flag must be resolved before a controlled substance prescription is dispensed.

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[146] *See, e.g.*, WMT_MDL000458935 ([redacted]

[147] WMT_MDL_000042987.
[148] WMT_MDL_000069077.
[149] WMT_MDL_000069746.
[150] WMT_MDL_000043015.
[151] WMT_MDL_000500661.
[152] Declaration of Joe Rannazzisi, *Holiday*, ¶ 56, p. 24.

CVS provided limited guidance on addressing certain red flags in 2012. CVS's 2012 "Protocol for Dispensing Narcotic Drugs for Pain Treatment" (ROPP-0061) stated: "Pharmacists should ordinarily only fill prescriptions if both the patient and practitioner reside within the geographic area served by the pharmacy - any exceptions should be extraordinary, and documented in the patient files."

The 2012 protocol further stated: "When dispensing a pain medication, such as oxycodone or hydrocodone, where you have no relationship with the patient and/or prescriber, you should verify with the practitioner the validity of the prescription, by requesting the diagnosis (request a diagnosis code) and other information relevant to whether the prescription should be filled or declined. Document the information on the back of the prescription."

In May 2013, CVS distributed the "Pharmacy Huddle Guide: Awareness of Red Flags Associated with the Non-legitimate use of Controlled Substances"[153] which states: "Once a Red Flag(s) has been identified, it is incumbent upon the pharmacist to resolve the Red Flag to his or her satisfaction as part of corresponding responsibility. If the pharmacist cannot resolve the red flag the prescription is returned to the patient.[154] If the additional information does resolve the Red Flag(s) in the professional judgment of the Pharmacist, then the prescription should be filled. Document the information that resolved the Red Flag on the back of the hard copy prescription."

Despite recognition that PDMPs are an "invaluable tool for Pharmacists to prevent controlled substances from being diverted or dispensed for non-medical purposes" there was no mandatory requirement to use PMPs until 2015[155] to resolve red flags: "Pharmacists must also access and review PMP data whenever they identify red flags that are not able to be resolved or are reasonably certain that a person may be attempting to obtain a Schedule II-V controlled substance for fraudulent, illegal or medically inappropriate purpose." As a CVS witness confirmed, at the time Ohio first offered it's PMP in 2011 with regulations to consult with PMP in specific situations, CVS did not have a written policy or provide clear guidance otherwise on its use.[156]

CVS told Pharmacists to "Document the information on the back of the prescription and in the patient's profile." Despite the instruction, CVS choose not to scan both sides of the prescription.[157]

In September 2016,[158] CVS required pharmacists to document certain information in the patient's profile in "the pharmacy computer system" and on the hardcopy prescription:

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[153] CVS-NYAG-0000033717
[154] *Id.* at CVS-NYAG-000033722.
[155] September 23, 2015, ROPP-0062, Prescription Drug Monitoring Program Policy, CVS-FLAG-000020952.
[156] Travassos Dep. 295:3-10, April 14, 2021.
[157] Travassos Dep. 239:2-25; 304:13-305:10.
[158] ROPP-0061 - 9/26/16 - Guidelines for Dispensing Controlled Substances CVS-FLAG-000020963)

"When dispensing a controlled substance medication, such as oxycodone, amphetamine, hydrocodone, clonazepam, etc. **where you have no relationship with the patient and/or prescriber**, you should verify with the practitioner the validity of the prescription, by requesting the diagnosis (request a diagnosis code) and other information relevant to whether the prescription should be filled or declined. Document the information on the back of the prescription and in the patient's profile in the pharmacy computer system."

It was not until July 2018 that CVS provided clearer guidance on the resolution and documentation of the resolution of red flags. At that time, CVS added a provision to their policy for dispensing controlled substances that instructed pharmacists "to document all steps taken to resolve red flags associated with controlled substance prescriptions in the patient profile." "The documentation must clearly justify the determination and appropriateness of the therapy dispensed. Documentation may include, but it is not limited to: diagnosis, PMP check, Prescriber conversation, treatment or taper plan. Any prescriber office conversation notations must also include the person spoken to, the date and the time."[159]

It was not until 2019, that CVS started to develop hard stop messages for certain red flags of diversion before a pharmacist could dispense an opioid.

According to some employees in CVS's Professional Practice Standards group, during crucial periods of the opioid epidemic, CVS did not audit its dispensing or patient records to ensure its pharmacists consistently and adequately documented red flag information. In fact, CVS cannot easily research the nature and frequency of red flags in its computer system.[160] Curiously, despite CVS's instruction to document the resolution of red flags, CVS had no consistent policy or practice to document those prescriptions its pharmacists refused to fill. Except for case of fraud, CVS pharmacist would potentially return the denied prescription to the patient.[161]

Walgreens

In 2012, for the first time, Walgreens' Controlled Substance Prescriptions & Good Faith Dispensing Policy required its pharmacists to use the PDMP where available to review the patient's profile to resolve and document any associated DURs, and contact the prescriber for verification to validate a controlled substance prescription. "If the prescriber cannot be reached, do not dispense the prescription."[162] The policy also listed a number of "examples that should alert a pharmacist to questionable circumstances" to determine if the "elements of good faith" are present prior to dispensing. If any of those issues were found, "the pharmacist has a responsibility to follow up with either the patient and/or prescriber for additional information to satisfy good

[159] ROPP-0061 7/10/18 V.11 Guidelines for Dispensing Controlled Substances CVS-FLAG-000013839.
[160] Travassos Dep. 159:9-25; 231:9-236:11.
[161] Travassos Dep. 254:22-258:16.
[162] WAGMDL00742666.

faith requirements." Importantly, the policy does not describe the "questionable circumstances" as red flags and it does not state that each red flag must be resolved before the prescription is dispensed.

At this time, Walgreens added to its policy a documentation requirement: "Document. It is imperative that pharmacists document all efforts used to validate good faith dispensing.

- Prescriber information: If the prescriber confirms the validity of the prescription, document the date, name of the individual spoken to and any other pertinent information such as diagnosis, previous therapy, length of treatment, etc. on the prescription hard copy and/or annotate the image.
- Patient information: If the patient provides an ID or other pertinent information such as medical history, health conditions, allergies, previous therapy, etc., scan any images into Intercom Plus as an "additional image," annotate the image, and/or document the information on the prescription hard copy. Update the information in the patient profile or in comments as appropriate.
- Elements of Good Faith: Document any information pertaining to the elements of good faith on the prescription hard copy and/or annotate the image."

"If the prescriber indicates that the prescription is not valid, document the prescription with the following: 'Rx not valid per prescriber' and do not dispense."[163]

In April 2013, Walgreens adopted the "National Target Drug Good Faith Dispensing" policy ("TD GFD") as a supplemental policy to the Controlled Substance Prescriptions and Good Faith Dispensing Policy and to "put teeth around GFD for high risk products."[164] For the Target Drugs (single ingredient Oxycodone, Hydromorphone, and Methadone),[165] pharmacists were instructed to complete the hardcopy "TD GFD checklist" (which helped to identify certain red flags, including early refill, potential doctor shopping, and "geographical proximity" between patient and pharmacy or prescriber and pharmacy) before filling the prescription, review patient comments in IC+, review DUR history, access the PDMP (if available), and attach checklist and PDMP report to the prescription hardcopy.[166]

Significantly, Walgreens deliberately omitted hydrocodone from the "Target Drugs" included in the TD GFD due diligence requirements. Back in 2013, Walgreens added hydrocodone to its TD GFD checklist in limited districts. At the same time Walgreens was drafting TD GFD, the DEA

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[163] June 2012 Controlled Substance Action Plan (WAGMDL00742642).
[164] WAGMDL01109078.
[165] WAGMDL00001246.
[166] *Id.*

and FDA were in the process of finalizing the rescheduling of hydrocodone, which Walgreens actively sought to defeat.[167]

Walgreens policies also required pharmacists to resolve and document red flags related to dangerous drugs combinations ("[c]arisoprodol in combination with narcotic analgesics such as oxycodone and benzodiazepines such as alprazolam") through a DUR.

Further, Walgreens generally instructed pharmacists to "document everything involving DUR in IC+." "Documentation," Walgreens acknowledges, "allows anyone to know what you, the pharmacist, was thinking at the time of fill – regardless of when they review, be it tomorrow, in a month or a year."[168]

[redacted]

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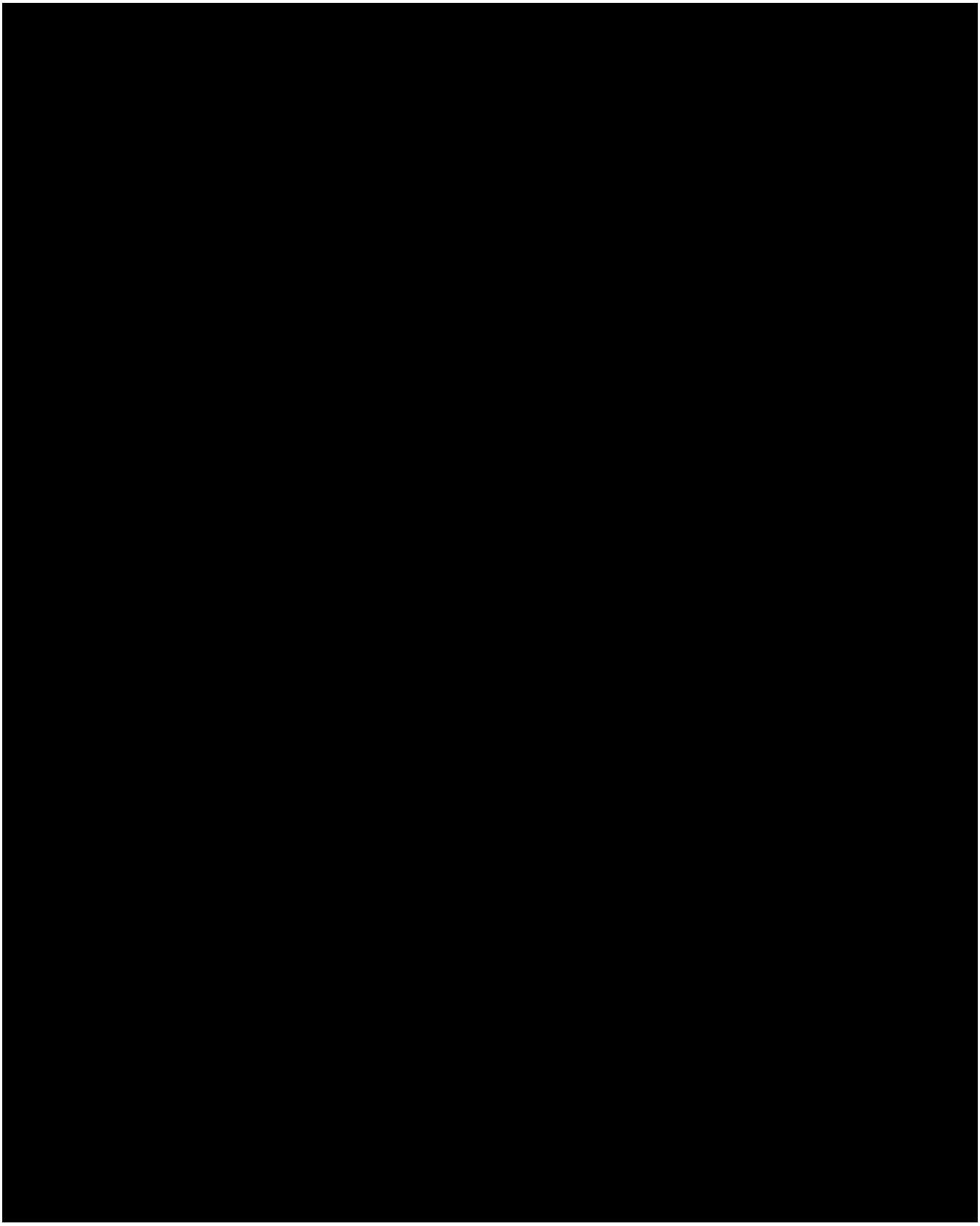
[167] CVS-MDLT1-000106705 at CVS-MDLT1-000106712; CAH_MDL2804_00011925.

[168] 9/10/13 "Prospective [DUR] at the Retail Setting" training presentation states: (00987029).

[169] [redacted]



[redacted]

Giant Eagle

Giant Eagle did not implement procedures for controlled substance dispensing until mid-2013. When it did, Giant Eagle required the pharmacist to "document the steps they have taken to verify questionable prescriptions, including any calls to the prescriber, conversations with the patient,

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179 [redacted].

180 [redacted].

181 [redacted].

182 [redacted].

medication history review, and notate on the prescription itself or in the computer system utilizing appropriate note fields." "This documentation must include:

- Name (first and last) of the individual to whom you spoke
- Date and Time of the conversation
- The phone number used to call the provider
- Brief summary of the substantive conversation"[183]

Giant Eagle instructed that "the Pharmacist must have cause before accessing the PDMP" and "when accessing a PDMP note the date and reason for accessing the database."[184]

I. Corporate Oversight Failures

Every pharmacy maintains dispensing data which could and should have been utilized by the Defendant pharmacies to prevent diversion. Dispensing data should have been reviewed by each corporate defendant to identify patterns of diversion and to create policies and procedures and training materials which proactively identified patterns of diversion. The large chain pharmacy companies should have used the information gleaned from that proactive analysis to inform their pharmacy staff of these patterns and to develop policies, procedures and training materials for its pharmacies. Each pharmacy should have also developed tools and programs to alert its pharmacists of these red flags at the time each prescription was presented. Some defendants developed these programs and alerts, but they did so in only the last two or three years.

Based on my review of documents and testimony provided by counsel, Defendants possessed dispensing data and other information collected at a corporate level. In a written response to deposition questions, each Defendant confirmed access to extensive and detailed prescription data and other information. Defendants, for example each collect dispensing data and store it in centralized data warehouses. Walmart also had access to "big data."[185] Responses and documents from defendants indicate certain defendants also have, for example, access to third party data or the ability to prepare charts and maps with visual representations.

Dispensing data for most large chain pharmacy companies is kept in central locations and retrievable through computerized means, as one former DEA Diversion Investigator, Ms. Ashley, agreed in deposition testimony.[186] The same former agent believed that these corporations'

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[183] HBC_MDL00191292.
[184] *Id.*
[185] *See infra* re CVS, WAG, Rite Aid, GE; WMT_MDL_000443289.
[186] Ashley Dep. 115:9-14.

dispensing data databases, if accessed properly, could do many of the same things as a PDMP, such as identify red flags associated with the data.[187] Ms. Ashley also agreed that it "would be reasonable to expect the pharmacies to access their own databases to look for red flags."[188] She further agreed that "if a pharmacy company is being vigilant in the face of a raging prescription opioid pill epidemic, access to that database of information would be important."[189] This testimony is consistent with what should have been the pharmacy industry practice throughout the period of the epidemic. In fact, most of the chain pharmacy defendants developed some types of programs at the corporate level to analyze their dispensing data for prescribers, patients and pharmacies potentially engaged in diversion, but they did not do so in a timely manner.

In 2013, CVS published an article in the New England Journal of Medicine highlighting the role of chain pharmacy data in anti-diversion. Mitch Betses, and Troyen Brennan, *Abusive Prescribing of Controlled Substances - A Pharmacy View*, N. ENGL. J. MED. 369;11, Sept. 12., 2013, at 989-991. The article described Chain Pharmacies ability to analyze chainwide data for "patterns" and to identify "high risk prescribers." *Id.* For purposes of the article, CVS documents indicate that CVS used data from its Caremark (Pharmacy Benefit Manager) arm, which also showed prescriptions filled at non-CVS pharmacies.[190]

Many of these red flags described in this report are easier to identify through the use of computer-generated calculations. For instance, it would be far easier and more accurate for information from the corporate dispensing program to alert a pharmacist if multiple patients present prescriptions for the same combination of drugs at different pharmacies within the corporation. Likewise, a program could have been written to calculate the distance between the patient and the prescriber or the patient and the pharmacy. If the distance exceeds 25 miles, the pharmacy dispensing program could issue a warning or alert to resolve the distance flag before the prescription is filled. Similarly, the software could have alerted pharmacists to known red flag combinations of drugs such as an opioid and a benzodiazepine. This is particularly useful when the prescriptions have been filled on different days, for different days' supply and at different pharmacies in the same chain. As another example, Chain Pharmacies could implement policies and procedures to alert of refusals to fill for certain prescribers or prohibit filling for those prescribers altogether. Defendants should have used the information available to them at the corporate level to guard against diversion.

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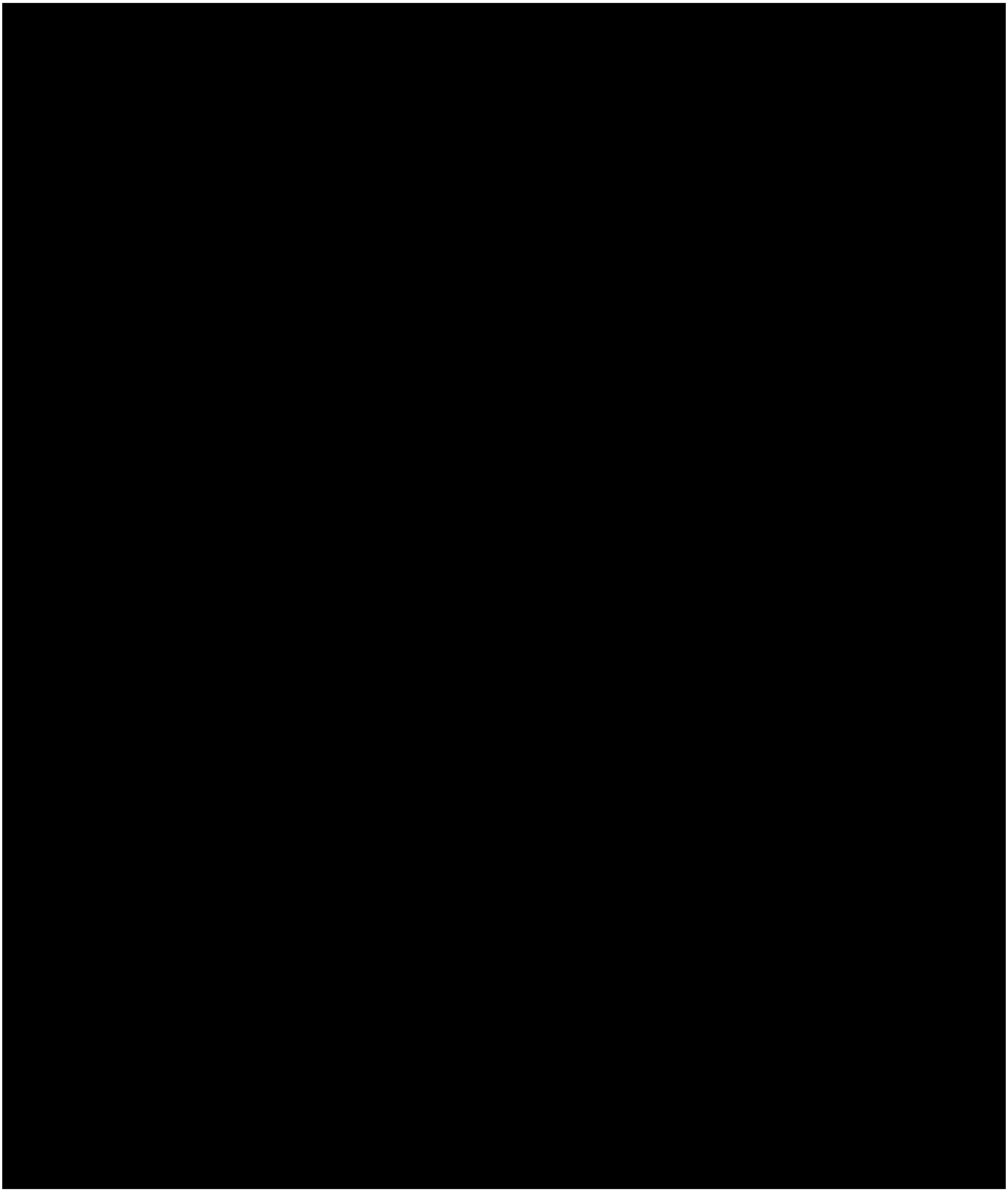
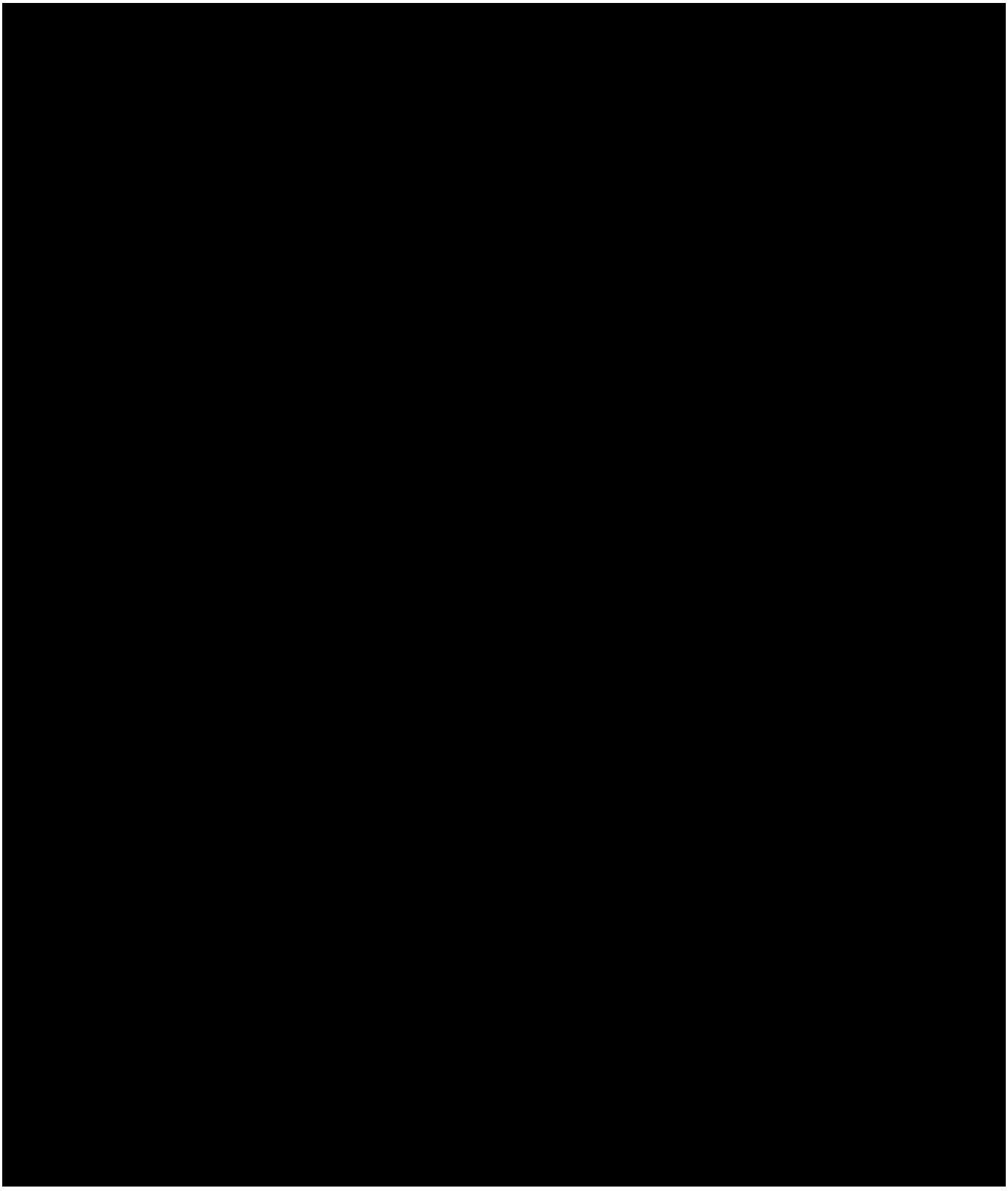
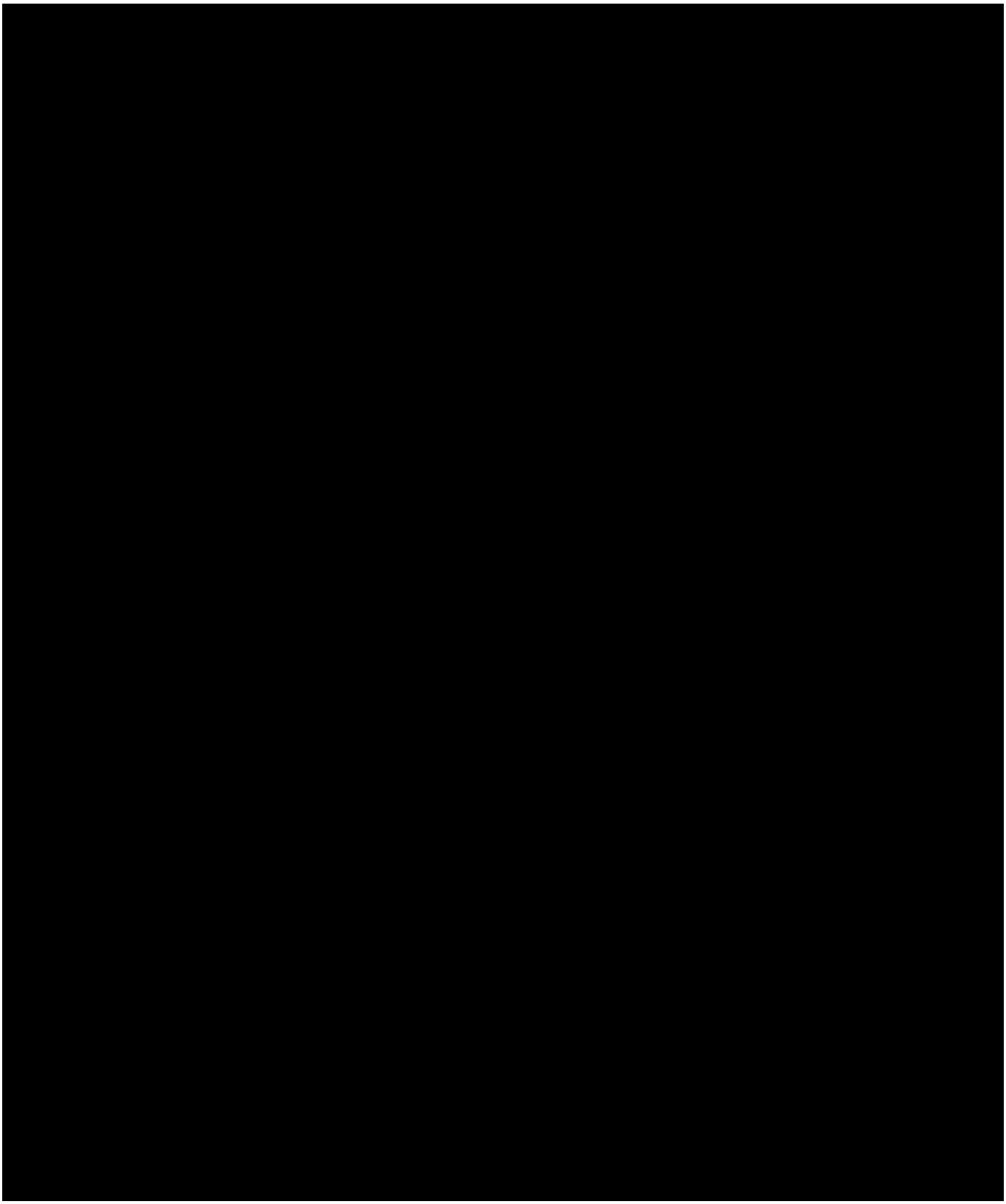
[187] *Id.* at 115:16-116:4.
[188] Ashley Dep. 132-34.
[189] Ashley Dep. 10:42.
[190] Tankut Dep. 177, Mar. 2, 2021.







[redacted]

Walgreens

Walgreens has available to it not only its own data, but also data from "vendors such as IQVIA/IMS.[223] Since "at least the mid-2000s," Walgreens has also had additional data sets

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[redacted]

[223] Walgreens Response to CR 30(b)(6) Topic 6.

available, including," data verifying prescriber DEA registration from LexisNexis," and "data on NDCs and DURs from Medispan/Wolters Kluwer."[224]

From 2004 to 2011, however, Walgreens did not have information or data available for pharmacists concerning whether a prescriber had disciplinary or law enforcement actions pending, to one district manager's knowledge.[225] To monitor patients paying for prescriptions with cash, it also has and "uses third-party data from healthcare plans."[226]

Despite having GFD policies, Walgreens routinely failed to provide its pharmacists the resources to effectively carry them out. For example, in 2012, when Tasha Polster was preparing to head up the new RX Integrity team (in charge of CSA compliance for dispensing and distribution), Tasha asked how a pharmacist could verify the validity of prescriber information, as required "in the original GFDP." Cheryl Creek, the "owner" of the GFD training said the available sources were either "horrible to use" and "need[] a password" or were "at least a month behind." She said she asked leadership "to look into this a while back but have not heard any progress."[227] Walgreens's documents evidence pharmacists felt pressured by management to fill prescriptions they were uncomfortable filling.[228]

From 2004 to 2011, Walgreens also had a computer system to show overutilization and underutilization.[229] This included "abuse/misuse" information, which would show attempts at "getting a prescription too early" or "multiple narcotics for the same issue."[230] To obtain that information, a pharmacist would access a system known as "Intercom Plus," which provided the information based on data loaded into the system that Intercom was analyzing and the dispensing data associated with a patients' prescriptions.[231] During that time frame, Walgreens pharmacists did have access to data demonstrating patients who were "doctor shopping," paid in cash or with insurance, or traveled long distances.[232] From 2004 to 2011, however, pharmacists did not have data to analyze whether a prescriber was prescribing a "cocktail trilogy" to a number of different patients.[233] Indeed, at the store level, Walgreens did not make any controlled substance metrics

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[224] Walgreens Response to CR 30(b)(6) Topic 6.
[225] Joyce Dep. 114-115.
[226] Walgreens Response to CR 30(b)(6) Topic 6.
[227] WAGMDL00931151.
[228] WAGCASF00046090; P-WAG-03450.
[229] Joyce Dep. 107.
[230] Joyce Dep. 107-108
[231] Joyce Dep. 108; Through its "Intercom Plus" system, it could display targeted messages at the register, as well as talking points for pharmacy staff. WAGMDL00862251.
[232] Joyce Dep. 115-116.
[233] Joyce Dep. 113.

available to pharmacists for specific prescribers.[234] Further, despite the fact that at the corporate level Walgreens utilized IMS for descriptive statistics around prescriber patterns, Rx Integrity team member Jon Arends was not aware of any consistent reports written using that data.[235] Instead, when a pharmacist or Walgreens team member had a concern about a particular prescriber ad hoc prescriber profiles were pulled.[236] However, these reports were difficult to interpret so corporate would have to assist with the analysis and interpretation of the reports.[237] Prior to May 2020, Walgreens had no dedicated field in its system for pharmacists to record that they received frequent combinations of prescriptions for known cocktails from a specific provider.[238] Similarly, prior to May 2020 Walgreens had no dedicated field in its system for Walgreens team members to record that a prescriber consistently wrote prescriptions for controlled substances for the same patient or for several different patients.[239]

A Walgreens district manager, Ohio Board of Pharmacy member, and former Walgreens pharmacy supervisor, testified that he did not know in 2012 that corporate had a mainframe computer compiling data as stores were dispensing opioids, and he could not recall seeing any reports from Walgreens corporate that analyzed the Walgreens stores under his management's dispensing for opioids.[240] He was not aware of whether Walgreens was analyzing its own dispensing data to look for red flags and saw no reports to that effect.[241] Earlier, from 2004 to 2011, pharmacists could rely on their own observations to see if a prescriber was prescribing the "cocktail trilogy to a number of different patients," but the data "didn't' show you the doctor's prescribing habits."[242]

Walgreens had the ability to assess dispensing of its stores relative to Walgreens pharmacies nationally, including with respect to overall volume, and changes in volume, proportion of controlled substances or frequently diverted drugs to total prescriptions, and percentage of cash prescriptions.[243] In January 2013, Walgreens also circulated internally a list of "Top 500 Potential Stores," showing highest-risk stores for oxycodone.[244] The same year, and following a "re-launch"

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[234] Arends Dep. 90, February 11, 2021.
[235] *Id*. at 91-92.
[236] *Id*. at 174.
[237] *Id*.
[238] *Id*. at 123.
[239] *Id*. at 124
[240] Joyce Dep. 103.
[241] *Id*. at 121.
[242] *Id*. at 113, 192.
[243] WAGMDL00700278.
[244] *Id*.

of the Good Faith Dispensing Policy,[245] Walgreens noted a "22% reduction in the number of patients receiving a cocktail monthly."[246]

Even so, as late as 2017, Walgreens refused to allow "blanketly" refusing to fill prescriptions from a prescriber, as long as the prescriber had an active DEA number.[247] Instead, it insisted pharmacists evaluate each prescription on a "case by case" basis.[248] Walgreens reinforced that policy in June 2018, for example, in response to concerns from a pharmacist at a store "consistently seeing high amounts of opioids also combined with benzodiazepines" from a prescriber who seemed to be "pre-writing 'diagnosis' codes on his scripts" to discourage calls or questions.[249]

Walgreens did have, however, the ability to analyze patterns in its data alongside other sources such as feedback collected in visits to local stores.[250] In analysis conducted as part of a December 2012, Walgreens developed a "Prescriber sanction pilot project.[251] Walgreens highlighted the insights it obtained about its stores in New Jersey and the Philadelphia area. "Data provided by LP Analytics" showed a "Prescriber Dashboard" with three months of information about opioid drugs prescribed, age and location of patients, and prescribing volume.[252] Walgreens determined, for example, that for one "[c]ash only prescriber," 65% of prescriptions were for oxycodone, and a full 92% of prescriptions were for controlled substances.[253] Walgreens had the ability to, and did create charts and a map to provide a visual representation along with the information.[254] Information collected from field visits also showed, for example, that a pharmacist "witnesses [a] stranger giving cash to multiple patient" to pay for pain prescriptions from a particular prescriber. Although an internal e-mail describes Walgreens as taking a "very conservative" approach, it still determined that six prescribers in the geographic area covered posed "a significant risk to Walgreens."[255] In August 2015 Walgreens began the Blocked Prescriber Process 2.0.[256] Select prescribers that did not meet the Walgreen Co. GFD Policy were to be excluded from the Walgreens Intercom Plus platform for controlled substances only.[257] It appears that the sanctioned

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[245] WAGMDL00707642.
[246] WAGMDL00708570 at 17.
[247] WAGMDL00002902
[248] *Id.*
[249] WAGMDL00091654.
[250] WAGMDL00745731.
[251] WAGMDL00745731.
[252] *Id.*
[253] *Id.*
[254] *Id.*
[255] *Id.*
[256] WAGMDL00094681.
[257] *Id.*

prescribers database still did not get fully integrated as an August 2017 presentation states: "We are developing a process to block select prescribers based on poor prescribing habits specifically for prescriptions for significant and unjustifiable quantities of controlled substance prescribed for chronic pain."[258]

In 2012, Walgreens also prepared a "Prescriber Index" that analyzed oxycodone prescribing by particular individuals, including out-of-state prescriptions, percentage of cash payments, and other detailed information.[259] The Prescriber Index was only available to corporate users.[260]

Since 2013-2014, Walgreens has used "automated quer[ies] of its "enterprise data warehouse" and runs reports, known as "GFD Opportunities reports," generated from data on its individual pharmacies and pharmacists.[261] A "GFD Opportunities" tool included information such as "Cash rank, Oxycodone IR rant, "target" drug quantity rank and target drug rate rank.[262] With the information available to it, Walgreens thus knew which pharmacists filled more controlled substances prescriptions that others. It appears from its written responses to discovery and documents produced, however, that Walgreens used the "Opportunities" report only for determining whether to provide "coaching" to pharmacists about filling prescriptions. Walgreens does not suggest it used the data to identify trends or patterns that were not available to busy individual pharmacists. Rather, it states that "Pharmacists analyze this information [dispensing data] in the course of filling prescriptions."[263]

In 2019, Walgreens described adding to its system a button on which pharmacists or staff could click to directly access a patient's history of controlled substances dispensing in the Patient Profile, and also to document a denial tied to a specific patient without an Rx number.[264] A monthly "store Index" report and "Top 100" store report also existed.[265] According to a "DEA Board Briefing Document," Walgreens was also making additional "indexing efforts" to include drugs other than oxycodone, which efforts included "trending data," hydrocodone, two drugs commonly abused with opioids (Alprazolam and Carisoprodol), as well as "top risk Prescribers, Patients, and Pharmacists.[266]

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[258] WAGMDL00033704 at WAGMDL00033712.
[259] WAGMDL00781632.
[260] WAGMDL00015204 at WAGMDL00015210.
[261] Walgreens Response to CR 30(b)(6) Topic 6; *see also* WAGMDL00708570.
[262] WAGMDL00708570.
[263] Walgreens Response to CR 30(b)(6) Topic 6.
[264] WAGMDL01064499.
[265] WAGMDL00897151.
[266] *Id.*

Prior to February 2021, Walgreens had no dedicated field in its system to calculate the distance between the patient's address and Walgreens pharmacy's address.[267] Similarly, prior to February 2021, Walgreens did not have any field that captured the distance between the patient and the prescriber.[268] Finally, in February 2021, Walgreens began piloting a system enhancement that to alert pharmacists when a set threshold between patient, prescriber and pharmacy was exceeded.[269] For the pilot Walgreens calculated the distances using zip codes and the formula for an urban setting was set to 30 miles.[270] As with other red flags, prior to May 2020, Walgreens did not have a dedicated field for team members to record instances where they found that there was an unusual geographic distance between the patient and the pharmacist or the patient and the prescriber that could not be explained.[271]

Prior to 2012 Walgreens Good Faith Dispensing policy was silent as to how a pharmacist was to record a refusal to fill within Walgreens' IC+ system. In late 2012 the Target Drug Good Faith Dispensing Policy instructed Walgreens pharmacists to use the patient comments field for refused prescriptions.[272] Walgreens also instructed pharmacists not to make notes regarding refusal to fill on the hard copy of the prescription "do not deface the prescription" and to return the prescription to the patient.[273]

In April 2013, when asked about the lack of sufficient space in IC+ for comments, and the build up of historical comments, rather than more room for comments, Walgreens RX Integrity instructed: "Please abbreviate as needed and **delete older comments or refusals from the patient profiles** to keep the notes current and accurate."[274]

Walgreens reiterated this instruction when asked if TD GFD Checklists for refused prescriptions could be scanned into a patients file stating; "Unfortunately, we do not have the memory storage space to scan these into IC+ across the entire chain. Please use the patient comments. Ensure the most recent TDGFD comments are showing, remove older comments, and abbreviate if needed."[275] Walgreens did not make the systems upgrades necessary to increase the space limitations for patient comments or to allow scans of the TD GFD Checklists because it was

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[267] Arends Dep. 131-132.
[268] Arends Dep. 131-132.
[269] Arends Dep. 132-134.
[270] Arends Dep. 132-135.
[271] Arends Dep. 121-122.
[272] WAGNYAG00006361; *see also* Arends Dep. 99-100.
[273] WAGNYNS00033698.
[274] WAGMDL00100054; *see also* Polster Dep. 319-329, March 1, 2021.
[275] WAGNYAG00006361 at WAGNYAG00006373.

waiting for new systems to be put into place.[276] Walgreens did not begin capturing refused TD GFD checklists in electronic format until May of 2020.[277] Prior to May of 2020, instructions to pharmacy staff were to document refusals of target drugs in the patient comments in the patient profile and the hard copy of the refused TD GFD Checklists would be stored in what Walgreens referred to as a "refusal binder" or "California folder."[278] Because the TD GFD refusals were not stored electronically, Walgreens pharmacies could not see TD GFD checklists filled out on patients at other Walgreens stores.[279] Furthermore, the TD GFD Checklists were not organized by patient, instead they were filed numerically according to prescription number.[280]

The limited GFD related audits Walgreens has conducted, despite its inability to pull complete GFD data, indicate that compliance with GFD and TD GFD has been poor. For example, in 2014 Walgreens discovered a pharmacist who failed to follow GFD for five to six months without being discovered by supervisors.[281] A December 2014 audit performed after the 2013 DEA settlement revealed that Walgreens's supervision and compliance failures continue. Among other failings, the audit team noted no formal monitoring program existed to confirm that pharmacies across the chain are complying with controlled substance documentation and retention requirements, no monitoring outside of the deficient "store walk program" existed to monitor target drug good faith dispensing requirements and no corporate reporting was being generated, and employees were failing to timely complete Good Faith Dispensing training, such that, at the time of the audit, over 35,000 employees had not completed their required training for that year. Management's response largely was to seek to incorporate additional compliance measures into the store walk procedure.[282]

In June and July 2015, Walgreens performed a BCI audit of a random sample of approximately 2,400 pharmacies to determine whether Walgreens "compliant with the policies/procedures put in place" regarding dispensing pursuant to Walgreens's agreement with the DEA.[283] As the audit progressed, RX Integrity and APS remarked "put your seatbelts on" because the audits were "not going great" and they would need to implement a "mitigation plan… to satisfy the MOA" for the non-compliance revealed by the audit.[284] In Walgreens's own words, the BCI audit "Results were unfavorable."[285] Fewer than 60% of stores were complying with TD GFD with respect to filled

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[276] Polster Dep. 333-334.
[277] Arends Dep. 99-100.
[278] *Id.*; Polster Dep. 56-57.
[279] Polster Dep. 52-53.
[280] Polster Dep. 57-58.
[281] WAGMDL00300924.
[282] WAGMDL00674321.
[283] WAGMDL00037616 at slide 3; WAGFLAG00092402 (RXI June BCI questions with sources).
[284] WAGMDL00045962.
[285] WAGMDL00037616 at 37618; *See also* WAGMDL00487576.

prescriptions, 1,160 stores did not have a single refused prescription, and an additional 1,182 stores had refused fewer than 25 prescriptions total in a nine-month period.[286] Only 63 out of 2,400 pharmacies had refused 26 or more prescriptions during that same nine months in 2015.[287]

Walgreens's policies reflect that in order to put "put teeth around GFD for high-risk products,"[288] beginning in April 2013,[289] Walgreens required its pharmacists to complete a Target Drug Good Faith Dispensing Checklist ("TDGFD Checklist") for every prescription presented to the pharmacist for certain "Target Drugs."[290] The "Target Drugs" are limited to single ingredient Oxycodone, Hydromorphone, and Methadone.[291] When presented with a Target Drug prescription, pursuant to Walgreens's policies, the pharmacist and technician must complete a TD GFD checklist as part of the pharmacist's evaluation of whether to fill the target drug prescription.[292]

From 2014-2020, the checklist was completed in hardcopy format.[293] After completion, the completed checklist was filed in the Walgreens store in which the prescription was presented.[294] Walgreens's document retention schedules require "records of actual prescriptions" including "controlled substances" to be retained for 11 years.[295] Walgreens documents confirm Walgreens applied this requirement to TDGFD checklists, and note that records "older than 5 years may be secured at an off-site location (*i.e.,* Iron Mountain)" rather than at the store.[296]

During CT3 discovery, Walgreens produced the hard copy TD GFD forms from the files of its CT3 stores.[297] In producing the documents, Walgreens designated which documents comprised TD GFD "checklists" and further specified from which store the checklists were being

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[286] WAGMDL00037616.
[287] *Id.*
[288] WAGMDL01109078 (P-WAG-03108).
[289] WAGMDL00316360 (P-WAG-05537); WAGMDL00744586 (P-WAG-05412).
[290] WAGMDL00573579 (P-WAG-05542.001).
[291] WAGMDL00001246 (P-WAG-01590.002); WAGMDL00001151 (P-WAG-05539).
[292] WAGMDL00674951 at WAGMDL00674989 (P-WAG-03448.001).
[293] *See* Arends Dep. 102, 103, 110, & 111.
[294] *Id.*; *See also* WAGMDL00674951 at WAGMDL00674989 (P-WAG-03448.001)
[295] WAGMDL00286244 at 286386 (P-WAG-05119); WAGMDL00286425 (P-WAG-05120).
[296] WAGMDL00487576 (P-WAG-03397).
[297] *See* Composite of Walgreens Production Cover Letters from 10/23/2020, 10/30/2020, 11/16/2020, 11/20/2020, 12/11/2020, and 12/21/2020.

produced.[298] Using the dates appearing on the face of the documents (the checklists require a date field), Plaintiffs' counsel assigned dates to each of the produced checklist documents.[299]

Walgreens has produced 19,272 TDGFD checklists from CT3 Stores over the following date range: December 2014 to December 2019.[300] During this same time period, Walgreens's dispensing data reflects that Walgreens dispensed 42,624 prescriptions of single ingredient Oxycodone, Hydromorphone, and Methadone from its CT3 stores.[301] Thus, it appears that Walgreens's CT3 pharmacists completed 23,352 ***fewer*** TDGFD checklists than were required by Walgreens's own policies during this time, failing to complete the required checklist for ***more than half*** of the subject prescriptions.

Even if one were to assume some TDGFD checklists that were five or more years old were stored offsite and not produced, the difference between completed TDGFD forms and dispensed prescriptions is still significant. From November 2016 to December 2019, Walgreens produced 17,567 TDGFD checklists from its CT3 stores. During this same time period, Walgreens dispensed 24,516 prescriptions of single ingredient Oxycodone, Hydromorphone, and Methadone from its CT3 stores.[302] Again, there is a significant difference between the number of dispensed Target Drugs and completed TDGFD checklists. During this five-year period during which documents should have been retained in Walgreens's stores, it appears that Walgreens's CT3 pharmacists completed 6,949 ***fewer*** TDGFD checklists than were required by Walgreens's own policies, failing to complete the required checklist for ***nearly 30%*** of the subject prescriptions.

These significant discrepancies in the numbers indicate that Walgreens pharmacists failed to follow Walgreens's TDGFD policies, and that Walgreens failed to enforce its own policies.

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[298] *See* Excel Export of Data Fields from Walgreens's CT3 TDGFD Checklist production (containing Walgreens Production Volume, Beginning Bates Number, Original Folder Path (Walgreens's designation of where document was obtained); Custodian (Walgreens's CT3 store number), and DocDate (completed by Plaintiffs' counsel).

[299] *See* Excel Export of Data Fields from Walgreens's CT3 TDGFD Checklist production, at "DocDate" field.

[300] *See* Composite of TDGFD Production Cover Letters; Excel Export of Data Fields from Walgreens's CT3 TDGFD Checklist production. Walgreens has only produced dispensing data through December 2019.

[301] *See* Walgreens dispensing data; Expert Report of Dr. Craig McCann at Exhibit 12K.

[302] *See* Walgreens dispensing data; Expert Report of Dr. Craig McCann at Exhibit 12K.

In the July 2015 BCI audit, RX Integrity noted dozens of stores dispensing opioids without performing the required checks.[303] In certain cases, the pharmacists were unaware of the GFD procedures or had been told by supervisors to disregard them.[304]

CVS

Before the 2008 to 2010 timeframe, CVS used the "RX2000" dispensing application as its pharmacy computer system to maintain dispensing data.[305] In the RX2000 application, the patient domain was separate from the prescriber domain and the two were not linked from a technical standpoint. DEA number, a license field, was part of the prescriber domain.[306] Not until CVS migrated to the "RxConnect" dispensing application in the 2008 to 2010 timeframe did a "notes" field linked to a patient become available." RxConnect is a centralized system, where all the stores enter the information, and all the data is stored.[307] That system is used by pharmacy operations teams and holds roughly two years' worth of data.[308] Data in the "CVS Pharmacy Data Warehouse," however, is retained for a minimum of 11 years.[309] Data in the prescriber domain is stored as long as the prescriber continues to have active prescriptions, and dates back to at least 1999.[310]

CVS used RxConnect to provide DUR alerts.[311] These include alerts for "high-MME" patients and "cocktail" prescriptions, as well as alerts related to forgeries.[312] A 2017, CVS Pharmacy DEA & Pharmacy Regulatory Training document states that "Patient Level Alert message now displays at Data Entry and Verification when a patient's profile has been identified as having prior prescription forgery incidents.[313]

No specific fields existed for an individual's actions or behavior, such as asking for opioids by a street name or appearing under the influence, however.[314] A corporate representative for CVS could not recall any field for prescriber notes existing.[315]

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[303] WAGMDL00039479.
[304] *Id.*
[305] CVS written response to Topic 6 and CR 30(b)(6) testimony re data.
[306] *Id.* at 120.
[307] *Id.* at 382
[308] *Id.* at 74-78.
[309] *Id.* at 106.
[310] *Id.* at 134-35.
[311] CVS Response to CR 30(b)(6) Topic 6.
[312] *Id.*
[313] CVS-NYAG-00003372.
[314] *Id.* at 102.
[315] *Id.* at 122.

In 2006, CVS implemented an analytical program that monitored its stores' ordering and dispensing for loss-prevention purposes.[316] CVS chose not to employ a similar analytical program to monitor its stores' dispensing for purposes of fighting diversion.

CVS states that in or around 2012, it implemented a Monitoring and Intervention Program, that is "operated by personnel in CVS's Professional Practices and Analytics group" and runs an algorithm on CVS's dispensing data.[317] CVS initially ran this algorithm only for oxycodone or hydrocodone products, or combinations involving these drugs; [redacted] In developing the algorithm, CVS used data from March 2010 to January 2012 and identified the 98th percentile for both volume and high-risk drug prescriptions as its initial cutoff.[319] The algorithm then went through several iterations until CVS had identified only 53 off a database of over 1.07 million prescribers.[320]

CVS could run reports showing, for example, the location of patients filling prescriptions for a particular prescriber at CVS pharmacies and the monthly volume dispensed to these patients.[321]

Around the same time in 2012-13, CVS also implemented a Controlled Substances Dispensing Program, which ran an algorithm on dispensing data to identify pharmacies to review. Initially, this algorithm also was only run for oxycodone-containing or hydrocodone containing products. In 2016, CVS added data for additional drugs to the algorithm.[322]

In 2014, CVS used the dispensing data available to it to set monthly limits on the amount of oxycodone and hydrocodone that each pharmacy could order.[323] It also states that its personnel had the ability to review dispensing data for purposes of suspicious order monitoring in connection with a computerized program that ran orders for review since 2009.[324]

In 2015, CVS began a program to analyze prescriptions from its stores that "exceed an MME threshold over a certain period of time."[325] It will them monitor the patients and "work with pharmacy teams where those patients have filled prescriptions," but does not further state what

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[316] *Id.*
[317] CVS written response to CR 30(b)(6) Topic 6.
[318] *Id.*
[319] Tankut Dep. Ex. 14, CVS-MDLT3-000026341.
[320] Tankut Dep. 182-183.
[321] CVS written response to CR 30(b)(6) Topic 6.
[322] CVS written response to CR 30(b)(6) Topic 6.
[323] CVS written response to CR 30(b)(6) Topic 6.
[324] CVS written response to CR 30(b)(6) Topic 6.
[325] *Id.* citing CVS-MDLT3-000111122.

this work involves.[326] All of the data analysis that was, for the first time, being conducted in 2014 and later, could have been conducted decades earlier given that it was based entirely on CVS' own dispensing data.

Walmart

According to the United States' complaint against Walmart, and Walmart documents, Walmart used a central email address to collect refusal to fill ("RTF") forms from Walmart pharmacists.[327] Walmart's policies governing refusals to fill based on the absence of a proper prescriber-patient relationship required that pharmacists notify Walmart's home office when they refused to fill a prescription.[328] Walmart then gathered the information into a monthly spreadsheet and sent it to some regional and store-level managers, but these spreadsheets did not always contain information identifying the doctors whose prescriptions had been refused.[329] Nor did Walmart reliably share RTF information with its pharmacists and pharmacy technicians, who needed it to evaluate suspicious prescribers and red flags.[330] According to the Complaint, "Walmart lacked any effective process to share red-flag information between pharmacists at the same store who did not have overlapping shifts or with "floating" pharmacists who worked only sporadically at any particular pharmacy." U.S. v. Walmart Inc. and Wal-Mart Stores, East. LP, No. 1:20-cv-01744, (United States District Court for the District of Delaware, December 22, 2020) at 148.

The refusal to fill forms completed by Walmart pharmacists contained valuable information that other pharmacists could have used to evaluate questionable prescriptions. For example, [redacted] Yet despite having RTF information available for years, Walmart did not make it readily available to

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[326] CVS written response to CR 30(b)(6) Topic 6.
[327] *See, e.g.*, WMT_MDL_000083636 (RTF from Store 2197, Cortland, OH re: prescriber Martin Escobar); WMT_MDL_000083608 (RTF from Store 1857, Mentor, OH re: prescriber Joseph Kousa). WMT_MDL_000069077, WMT_MDL_000069117, WMT_MDL_000042957, WMT_MDL_000042987, WMT_MDL_000069087, WMT_MDL_000067636.
[328] WMT_MDL_000069077, WMT_MDL_000069117, WMT_MDL_000042957, WMT_MDL_000042987, WMT_MDL_000069087, WMT_MDL_000067636.
[329] WMT_MDL_000458936 (Oct. 2012 RTF spreadsheet report).
[330] WMT_MDL_000458935 (H&W Sr. Dir. sends RTF spreadsheet to managers but instructs it not be shared with anyone else); WMT_MDL_001004133 (Reg. Mgrs. complain about lack of access to RTF reports).
[331] WMT_MDL_000287293.
[332] WMT_MDL_001163282 (RTF form 4/10/15).

pharmacists.[333] [redacted] and could have similarly provided alerts of RTF information collected.[334]

[redacted] Even as recently as 2019, Walmart did not consistently provide RTF information to its pharmacists.[338] Pharmacists were often left to rely on word of mouth or reach out to the compliance department when they needed RTF or red flag information.[339] The compliance unit, meanwhile, "had 'not invested a great amount of effort' in data analysis."[340]

In 2018, the Home Office was on notice that some pharmacists may not even have been aware of the dispensing red flags they should consider in evaluating prescriptions. Reportedly, [redacted]

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[333] Townzen Dep. 199: 1-17, Feb. 12, 2021.
[334] WMT_MDL_000451385 (Relay Health edit re: prescriber licenses); WMT_MDL_000068641 (POM 1006 discusses drug utilization review alerts).
[335] WMT_MDL_000048797.
[336] WMT_MDL_000312847/848 (2/2/15 email re: RTF pilot program and instructions).
[337] WMT_MDL_000508416; *see also* WMT_MDL_000404558 (no feed established between Archer and Connexus; and it would be a "substantial undertaking" to do so).
[338] WMT_MDL_000444529 (Walmart had rolled out RTF and Blanket Refusal to Fill ("BRTF") functionality in Connexus to 15 stores as of April 2019, but had to pause rollout due to "technical limitations"); WMT_MDL_000500350 (working through glitches in RTF Tool in August 2019).
[339] WMT_MDL_001075183 (pharmacist requests past RTF data for consistency in evaluating prescriptions; Nelson falsely responds that POMs require the store to keep its own records of past RTFs); WMT_MDL_000366467 ("While pharmacists are still in the best position to determine whether individual prescriptions are appropriate, we have access to information at the Home Office that is not available to our pharmacists.").
[340] WMT_MDL_000232072.
[341] WMT_MDL_000007350.
[342] *Id.*

Walmart states that [redacted]

Walmart's failure to analyze and communicate red flag data about suspicious prescribers was due to a misalignment of priorities. For years, Walmart's Global Investigations [redacted]

In 2017, Walmart [redacted]

As late as 2018, Home Office employees expressed concern that pharmacists were not aware of and did not have access to certain red flag data points considered by the Home Office controlled substance analysts.[347] A 2018 email chain describes Walmart team members as "caught off guard" by Home Office analyst questions and "red flags they may not be aware of," as well as that "[t]hey [redacted] However, by this time, Walmart's efforts were too little, too late – the prescriber and the pharmacy to the "Connexus the pharmacist has to check."[349]opioid crisis had raged on for years.

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[343] Townzen Dep. 9.
[344] WMT_MDL_000370703 (9/12/17 email in which Walmart's [redacted] WMT_MDL_000463402.
[345] Walmart Response to CR 30(b)(6) Topic 6.
[346] Walmart Response to CR 30(b)(6) Topic 6.
[347] *See* WMT_MDL_000007850.
[348] *See supra*. Section 1.F.
[349] WMT_MDL_000007350.

Giant Eagle

In June 2013, Giant Eagle's compliance department drafted a detailed 47 page long "Giant Eagle Pharmacy Controlled Substances Manual" containing approximately 20 pages on dispensing red flags and due diligence in order to address what Giant Eagle recognized as the "epidemic" created by the "abuse of prescription drugs."[350] The document breaks out red flags and prescription due diligence steps applicable to each stage of the prescription fill process, and for each pharmacy employee who might be involved in filling the prescription (listing, e.g., "Red Flags for Drop-Off", "Red Flags for Data Entry", "Red Flags for Fill," etc.). However, Giant Eagle never implemented this policy and never provided the document to Giant Eagle pharmacies. Instead, Giant Eagle chose to implement a four-page policy with significantly less detail and instruction. When asked why Giant Eagle failed to provide the detailed policy to its pharmacists, Giant Eagle's corporate representative concerning dispensing testified that to "consolidate and put things together in place" for the pharmacists "would give them a false sense of security," and that, instead, Giant Eagle believed it would be better to pick up on the information bit by bit, from sources including continuing education , staff meetings, the Giant Eagle intranet, and emails.[351]

A 2016 document reflects the ability to "[u]se the data warehouse to find out the doctor's prescribing habits across the GE brand" and could use both the data warehouse and "EPS to research the doctor's patients."[352] There does not appear to be earlier discussion of this ability, nor is it referenced in training materials produced by Giant Eagle and reviewed for purposes of this Report. The same memo suggests Giant Eagle had a variety of geographically-based investigative tools including the doctor zip code in relation to his or her patients' zip codes and in relation to that pharmacy.

While Giant Eagle pharmacists were able to run a report on prescriptions filled at Giant Eagle written by a particular doctor, the pharmacists only had access to data for prescriptions filled for that doctor at their own store. Giant Eagle did not give pharmacists the ability to run to chain-wide dispensing reports regarding particular doctors.[353]

With regard to supervising red flag compliance, the only report Giant Eagle corporately ran with any regularity was a "Threshold Report" that, starting in 2013, reported on the amounts of drugs distributed to particular Giant Eagle pharmacies.[354] No other reports were run on a regular basis. Prior to that time, Giant Eagle testified that it could have utilized an inventory system called SupplyLogix to run threshold reports, but its 30b6 witness was unable to provide any clarity or

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[350] HBC MDL00032653; Tsipakis Dep. 161-182, Mar. 17, 2021.
[351] Tsipakis Dep. 161-182.
[352] HBC_MDL00059780.
[353] Tsipakis Dep. 50-55.
[354] Tsipakis Dep. 70-90.

specificity regarding what those reports were or how often they were run or utilized.[355]The global SupplyLogix reports were not tools that the pharmacists could create in order to inform whether or not to dispense a particular prescription.[356]

J. Corporate Policies Failed to Make PDMP Checks Mandatory.

As described above, PDMPS, such as OARRS, may provide valuable information to aid dispensing decisions. In Ohio, OARRS provided an additional source of prescription history information, not only concerning prescriptions written in Ohio, but through information sharing with other state PDMPs as well. The Ohio BOP's *OARRS Fact Sheet for Pharmacists* states that: "OARRS is currently linked to other states via PMP InterConnect®."[357]

Information from the National Association of Boards of Pharmacy ("NABP"), for example, describes more than 40 states as having signed "a memorandum of understanding with NABP to participate in NABP PMP InterConnect®" as of May 18, 2016.[358] Presently, all states, with the exception of Missouri, which enacted county-wide agreements with NABP, have operational and incterconnected PDMPs.

As described below, however, pharmacists faced time-pressure from metrics Defendants imposed. Meanwhile, Defendants' policies for years failed to require that pharmacists check OARRS before dispensing opioid prescriptions, despite clear recognition of the critical role that such PDMPs play in fighting diversion.

Prior to 2010, Walmart did not provide its pharmacists access to state PDMP databases.[359] Walmart's choice to do so in 2010 appears to have been driven by the negotiation process surrounding the DEA MOA, which affirmatively required the company to provide PDMP database access in participating states.[360] Walmart did not require its pharmacists to check PDMP databases for any category of opioid drug as a matter of corporate policy until mid-2012, when it imposed a

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[355] Tsipakis Dep. 92-109.
[356] Tsipakis Dep. 108-109.
[357] Ohio State Board of Pharmacy, OARRS Fact Sheet for Pharmacists, at 2, (Updated 9/6/2019), https://www.pharmacy.ohio.gov/Documents/Pubs/Special/OARRS/OARRS%20Fact%20Sheet%20for%20Pharmacists.pdf.
[358] https://nabp.pharmacy/newsroom/news/over-forty-states-are-now-members-of-pmp-interconnect/.
[359] WMT_MDL_000424885.
[360] WMT_MDL_000043490.

requirement to check before filling oxycodone 30mg IR prescriptions.[361] This requirement did not extend to other widely abused opioids, such as oxymorphone IR or fentanyl. Additionally, access to individual state PDMP databases could not allow pharmacists to check for pharmacy shopping crossing state lines—a situation that meant, as Walmart recognized in internal documents, that "[p]harmacists lack visibility to prescription monitoring program (PMP) information that is needed to properly execute their 'corresponding responsibility' as required by the Controlled Substances Act."[362] This situation continued until 2017, at which point Walmart introduced a system to check PDMP databases across state lines for opioids automatically. One of the benefits Walmart identified of an automatic PDMP check system was that it would allow for "quicker fill time."[363]

[redacted][366][redacted][369]

I. Corporate Performance Metrics Undermined Compliance. Defendants Used Data for Performance Metrics and Sales

A prime metric that is collected, analyzed, and enforced as evidence of the overall corporate control of the individual pharmacies and pharmacists are performance measures relating to the dispensing of prescriptions, customer wait times, and sales. The information reviewed clearly

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[361] *Id.*
[362] WMT_MDL_000508830 (5/22/15 New Technology Requests at p. 6).
[363] WMT_MDL_000003145 (8/4/16 summary of NarxCheck program).
[364] [redacted].
[365] [redacted].
[366] [redacted].
[367] [redacted].
[368] [redacted].
[369] [redacted].

demonstrated that the corporate entities collected data from the individual pharmacies and analyzed the data to determine and monitor performance metrics.

Walgreens' "Pharmacy Manager Bonus Program" and "Staff Pharmacist Bonus Program" documents both instruct that "[t]he best evidence of a well-run pharmacy is the increase in prescriptions and pharmacy sales."[370]

Walgreens also used oxycodone dispensing metrics to target stores with low oxycodone dispensing numbers for potentially increased dispensing. Specifically, in 2010, Walgreens asked supervisors to "look at stores on the bottom end" of oxycodone prescribing and questioned "[a]re we turning away good customers?"[371] Supervisors and district managers were instructed to review the low dispensing stores and to use "CEs" from Walgreens.[372] Additionally, in 2011, a Walgreens project to "Increase Rx Sales and prescription Counts" instructed pharmacies to "improve C2 business."[373] C2 is shorthand for Schedule 2 controlled substances. The DEA's September 2012 Order to Show Cause and Immediate Suspension of Registration highlighted that Walgreens had a corporate policy encouraging increased sales of oxycodone.[374] Metrics focused on increasing opioid prescriptions conflict with corresponding responsibility to ensure each of those prescriptions is appropriate and valid.

Yet, even after its $80 million settlement with the DEA, in 2014, Walgreens' "RX Integrity" department created a "Pharmacist Controlled Substance Dispensing Opportunities" tool to "identify pharmacists that are dispensing a low rate of controlled substances," and help pharmacists "feel more comfortable in filling controlled substances."[375] This specifically focused on pharmacists dispensing low rates of opioids like "hydromorphone, oxycodone, methadone… hydrocodone," and the drugs comprising the rest of the "holy trinity" or other "cocktails," such as "carisoprodol… [and] alprazolam."[376]

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[370] *See* WAGFLDEA00000001; WAGFLDEA00000007.
[371] *See* WAGFLDEA00000812.
[372] *See* WAGFLDEA00000812. Importantly, many of Walgreens "CEs" or continuing education related to opioids was sponsored by opioid manufacturers and their trade organizations. For example, Walgreens suggested that its pharmacists attend a CE entitled "Pharmacist's Role in Pain Management - A Legal Perspective". WAGFLDEA00000659. This CE was sponsored by Purdue Pharma. WAGMDL00766952. The second "CE" incorporated into Walgreens's dispensing training program, "Navigating the Management of Chronic Pain: A Pharmacist's Guide" was sponsored by opioid manufacturer Endo Pharmaceuticals and disseminated information designed to broaden the market for opioids. WAGMDL00766955.
[373] *See* WAGMDL00698804.
[374] WAGMDL00387654-666.
[375] *See* WAGMDL00099514.
[376] *See* WAGMDL00099514.

CVS incentive compensation plans encouraged opioid sales. For example, the 2010 Pharmacist Incentive Plan, an incentive plan that included opioids and bonuses based on Number of Scripts filled, read that the "objective of all CVS incentive plans is to motivate employees to exceed top line results and maximize store profit…."[377] Similarly, supervisor and management incentive plans were also all about driving profit. For example, the 2012 Pharmacy Supervisor Incentive Plan provided that "Pharmacy Supervisors have the opportunity to earn up to 54.6% of their base salary in incentives, based on Management Controlled Profit modified by a few factors including Script Count (number of scripts filled).[378] Again, leaving no doubt as to the push to drive sales, the Plan Objective was to "reward Eligible Participants … for their role in driving performance."[379]

[redacted]

[redacted]

[redacted]

[377] *See* CVS-MDLT1-000061039.
[378] *See* CVS-MDLT1-000060922.
[379] *Id.* at 60923.
[380] [redacted]
[381] [redacted]
[382] [redacted]
[383] [redacted]
[384] [redacted]
[385] [redacted]

[redacted][90]

In 2010, Walmart analyzed store level prescription data to identify the most commonly dispensed non-CII drugs—including, at the time, hydrocodone—and to move those drugs closer to the front of the pharmacy so that store associates did not have to walk as far to get them and could fill prescriptions faster.[391] A Walmart Quality Assurance manager observed that most stores had identified hydrocodone and diazepam—a drug widely used in opioid cocktails—to the fast movers section.[392]

CVS utilized a MyCustomer experience scorecard to track pharmacy staff's customer service and sales performance such as whether a drug was in stock, the amount of time to fill a prescription, whether the customer was greeted by name, among many other factors. None of those factors included corresponding responsibility.[393]

The 2019 CVS WeCare Workflow Metric Toolkit is explicit that filling scripts in less than 15 minutes is critical. "The purpose of the WeCARE scorecard is to help meet our customers' expectations by empowering the Pharmacy team members to utilize key metrics that focus on workflow balance and problem resolution."[394] The WeCARE scorecard focuses on activities that allow the prescriptions to be filled quickly: "WeCARE reporting for 2019 will help store teams better assess and deliver superior service through optimal workflow, by removing the existing

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[386] [redacted].
[387] [redacted].
[388] [redacted].
[389] [redacted].
[390] [redacted].
[391] WMT_MDL_000420219.
[392] WMT_MDL_000425955.
[393] Aivazis Dep. 168:24-174:20.
[394] *See* CVS-MDLT3-00006734 at 00006735.

ratings scale and point distributions and replacing them with a new metric; **%Order Ready. This new metric will be the focal point of the WeCARE program.** The outcome of whether prescriptions were ready for patients on time will replace the WeCARE score so teams can focus on what is most important; the customer."[395] The document outlines that 70% of customers would wait for prescriptions if given the opportunity and that "[p]roviding waiting prescriptions in 15 minutes or less is a differentiator of CVS/pharmacy compared to our competition in meeting customer expectations."[396] The %OrderReady metric measures the percentage of prescriptions that were ready on-time. However, not only does CVS indicate in this same document that providing prescriptions in 15 minutes or less is critical, but it also indicates that one of the "Key Contributing Factors" in satisfying the Waiters Served as Promised Metric is a "**Wait Time** 15 minutes or less." Findings from multiple proceedings before the State Board of Pharmacy, State of Oklahoma specifically indicated that "All 'wait time' measurements should be removed from consideration for the purposes of any employee bonuses or compensation decisions. Using 'wait time' history as a factor in pharmacy management metrics creates an unnecessary burden on every pharmacist while on duty, encouraging pharmacists to work in a hazardous way, putting the safety of the public at risk."[397]

Defendants Imposed Performance Metrics that Impacted their Employees' Efforts to Meet Standards Care and Compliance Obligations

A DEA registrant is also responsible for creating a work environment that enables its pharmacy staff to detect and prevent diversion. Accordingly, former DEA diversion investigator Demetra Ashley testified that she believed the duty to provide tools to prevent diversion under Section 1301.71 includes providing a work environment that allows pharmacists to fulfill their corresponding responsibility to fill only legitimate prescriptions.[398] Adequate staffing is also important.[399] Further, both strict time limits that deprived pharmacists of enough time to investigate red flags and requiring quotas on prescriptions filled sounded unreasonable her.[400] Corporate performance metrics focused on increasing dispensing of prescriptions, increasing sales, and lowering customer wait times can place pharmacists in conflict with legal requirements such as corresponding responsibility. Emphasis is placed on meeting the performance metrics and

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[395] *Id.* at 00006737.
[396] *Id.* at 000060741.
[397] *See e.g.*, In the Matter of the Complaint Against: CVS Pharmacy No. 1049, State Board of Pharmacy, State of Oklahoma, Case No. 1593.
[398] Ashley Dep. 171-74.
[399] *Id.*
[400] *Id.*

directed away from the due diligence needed to properly evaluate and assess a prescription's appropriateness and validity.

Documents and testimony obtained through discovery in this matter show that the Defendants placed significant pressure on their pharmacists to fill increasing numbers of prescriptions in as little time as possible. For example, Walgreens' pharmacy policies emphasized the company's focus on high volume: "The best evidence of a well-run pharmacy is the increase in prescriptions and pharmacy sales."[401] Walmart managers told pharmacists to "[h]ustle to the customer, hustle from station to station" because filling prescriptions "is a battle of seconds."[402] A Lake County Walmart pharmacist (whose 2013 prescription goal was set at more than 120,000 prescriptions) testified that she struggled with time management and the competing demands on her time between filling prescriptions, talking to patients, and talking to prescribers.[403] The three main objectives on her performance reviews were customer service, sales, and profit.[404] As a pharmacist, she understood that Walmart expected annual increases in pharmacy sales and profits—and that her performance rating impacted her raises.[405]

Defendants' unrealistically promised customer wait times for prescriptions of 20 minutes or, in some cases, less.[406] In the usual and customary practice of pharmacy such arbitrary metrics do not allow sufficient time for the pharmacist to complete all the necessary procedures required to assess the appropriateness and validity of a prescription and safely dispense the medication. Thus, for example, responses by Walmart pharmacy staff to an October 2014 survey (quoted at length in the United States' 2020 complaint against Walmart) include comments that "We are not adequately staffed for safely filling the volume of prescriptions that are brought to this pharmacy. We are spread too thin," "Our [District Manager] continually sends our pharmacy nasty emails and chastises us for not having a [sic] high enough numbers in our input and fill accuracy and times. We are therefore instructed to cheat the system," and "Us being critisized [sic] b[y] our Health and Wellness Director about not getting prescriptions out in 20 minutes causes the pharmacy to take short cuts and affects patient safety."[407] Associates in Walmart pharmacies in Ohio expressed concerns that the stores had too few technicians, burdening pharmacists with more work.[408]

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[401] WAGFLDEA00000001; WAGFLDEA00000007
[402] WMT_MDL_000691809; WMT_MDL_001177305.
[403] Militello Dep. 130:19-24, March 19, 2021.
[404] *Id*. at 119:20-120:15.
[405] *Id*. at 125:20-126:5
[406] Walgreens default promise time for prescriptions is 15 minutes. WAGMDL00779646.
[407] WMT_MDL_000661957.
[408] WMT_MDL_000450160–61 (noting that the lack of technician hours resulted in some pharmacists handling 25% of prescription filling in one month).

Concern has also been expressed that there is a lack of proper training for technicians, and rushed customer service, as a result of time constraints.[409] Adding to the stress, Walmart pharmacists could be called to work at various stores within one hour drive of their home[410] and, until 2017, could be placed on a plan of 72-84 hours per pay period.[411]

Further, the Defendants enforced the metrics, and pharmacy employees reported being criticized and punished if they did not meet volume and speed expectations.[412] Managers compiled prescription volumes and wait times data for presentation to and review with pharmacists.[413] Walgreens even created a tool to detect pharmacists who were dispensing too few opioids and another tool to track the time to fill a prescription.[414] Likewise, a CVS pharmacy employee reported that every prescription was timed, and pharmacy staff would be notified if they fell behind. Numerous employee reports and surveys show that these metrics created high stress and unsafe work environments.[415]

Documents reviewed show that opioids were included in multiple Defendants' performance metrics until 2013.[416] Under CVS' pharmacist incentive plans, a pharmacist's bonus was tied in large part—as high as 50% in 2006—to "number of scripts." CVS included scripts for Schedule II drugs in its incentive plans until 2013.

From 2012-2014, Walmart pharmacists were eligible for performance-based bonuses based, in part, on prescriptions filled with a pre-set goal.[417] Pharmacists and other pharmacy staff could double the base bonus ("Additional MIP" bonus) if the pharmacy dispensed 190,000 or more

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[409] *Id*.
[410] Militello Dep. 59:12-15.
[411] WMT_MDL_000056349-50.
[412] WAGCASF00113475 (Walgreens employee said they would lose hours).
[413] Walgreens report of verified by promise time totals WAGFLAG00080494 at slide 23.
[414] Walgreens average prescription wait times were monitored using a tool called the PhLOmometer WAGNYNS00055995.; *see also* WAGMDL00099513, Walgreens tool to track low dispensing stores.
[415] Walgreens Pharmacy Managers' feedback stating that pharmacists did not have enough time to do health testing and MTM effectively and that a lack of resources kept them from being effective and consistent. The feedback also indicated that pharmacy managers were "[s]truggling to keep our heads above water let alone manage." WAGMDL01166994. Walgreens Tata Consultants Presentation detailing "High Stress" and "errors resulting from stress" states "we heard multiple reports of improper behavior" that was "largely attributed to the desire" to meet a corporate metric known as "promise time," which ensures that patients get prescriptions filled within a set amount of time. TCS00000196 at TCS00000229.
[416] CVS-MDLT1-000060922, CVS-MDLT1-000060968, CVS-MDLT1-000060989, CVS-MDLT1-000060930, CVS-MDLT1-000061017, CVS-MDLT1-000060975, CVS-MDLT1-000060956.
[417] WMT_MDL_000043533.

prescriptions.[418] Walmart was aware by early 2013 that the DEA had expressed concerns that bonus incentives for dispensing controlled substances could "lead to bad pharmacist decisions because they know they will get something out of filling scripts."[419] Yet, Walmart did not exclude controlled substances from its bonus plan until 2015—and then it excluded them only for the "Additional MIP" portion of the plan.[420]

Walgreens had a bonus program that factored the number of scripts, including for controlled substances, into bonus calculations. Walgreens only agreed to exclude controlled substance prescriptions from bonus calculations beginning in 2014 as part of the 2013 DEA settlement. The immediate impact was a 21% reduction in the number of stores purchasing 80mg (or the highest dose) OxyContin, which suggests that tying pay to controlled substance prescriptions can create the wrong incentives to fill those prescriptions. In April 2014, a Walgreens "RxIntegrity" presentation focused on Walgreens "Market 25," but also assessing "average market" trends, reported that "pharmacists [were] not being too strict with GFD, nor [were] they losing volume."[421]

Even though Walgreens had adopted a "Good Faith Dispensing" (GFD) Policy, which it relaunched in June 2012 in response to the DEA action described above, which required pharmacists to take certain steps before dispensing certain controlled substances, as described above, documents show that Walgreens kept the pressure on, telling pharmacy staff "GFD concerns doesn't relieve you from trying to attain the numbers that have been set for you."[422]

In addition, even after controlled substances were taken out of performance metrics in 2013, the pressure to meet high volume targets for other prescriptions was still there, which meant that pharmacists still did not have the time or incentive to take the time to properly examine controlled substance prescriptions and identify and resolve any red flags for diversion. Also, there was still pressure to fill controlled substance prescriptions and to do so quickly because performance metrics focused on profitability remained.

In one document, a Walmart manager appears to recognize that the corporate goal of increasing sales is not compatible with detecting and preventing diversion. Responding to a question from a regional manager in 2015 about documenting pharmacists' concerns about doctors believed to be operating pill mills, Walmart's Director of Health and Wellness Practice Compliance wrote: "We have not invested a great amount of effort in doing analysis on the data since the agreement

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[418] *Id*. ("Additional MIP").
[419] WMT_MDL_000357869.
[420] WMT_MDL_000043588.
[421] WAGMDL00673006 at 3. Market 25 consisted of Indiana, Kentucky, and West Virginia. Similar results reported for Market 3, Florida. WAGMDL00018179 at 4.
[422] WAGMDL00302949.

[requiring such reporting] is virtually over. Driving sales and patient awareness is a far better use of our Market Directors and Market manager's time."[423] Pharmacy employees also reported that performance metrics focused on high volume and speed meant taking "shortcuts" that affect patient safety.[424]

Giant Eagle admits that its pharmacists' "Annual Performance Reviews included goals to generally "Increase Profitability," "Increase Sales," and "Increase Script Volume," (or some combination thereof)" and that "those goals were assessed based on profitability, sales, and script volume for the entire pharmacy at which the pharmacist worked."[425]

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[423] WMT_MDL_000232072.
[424] WMT_MDL_000661952 - WMT_MDL_000661981.
[425] Giant Eagle's Written Answer to Topics 3 in Plaintiffs' Dispensing General 30b6 Notice, at pp. 10-11. *See also* RX Bonus Plan documents cited in the response: HBC_MDL00191129; HBC_MDL00191120; HBC_MDL00191122; HBC_MDL00191127; HBC_MDL00191167; HBC_MDL00191162; HBC_MDL00191178; HBC_MDL00191181; HBC_MDL00191164.
[426] [redacted]
[427] [redacted]
[428] [redacted]
[429] [redacted]
[430] [redacted]
[431] [redacted]

[redacted][437]

A number of national and international professional pharmacy and public health organizations have called for restrictions or an end to performance metrics that focus on high volume and speed because they cause distractions, impair professional judgment, and jeopardize patient safety and public health. In June 2013, NABP passed Resolution No: 109-7-13 "Performance Metrics and Quotas in the Practice of Pharmacy" to help "regulate, restrict, or prohibit the use in pharmacies of performance metrics or quotas that are proven to cause distractions and unsafe environments for pharmacists and technicians."[438] The resolution resulted from concerns expressed to a number of state boards of pharmacy by pharmacists about the impact on patient care caused by performance metrics that focused on time guarantees and percentage of prescriptions filled within a specified time period, for example. The member jurisdictions of NABP unanimously adopted the recommendation for NABP to assist its member boards of pharmacy to regulate, restrict, or prohibit the use in pharmacies of performance metrics or quotas that are proven to cause distractions and unsafe pharmacy environments. In addition, NABP will propose amendments to

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[redacted]

[438] NABP, Performance Metrics and Quotas in the Practice of Pharmacy (Resolution 109-7-13) (June 5, 2013), https://nabp.pharmacy/performance-metrics-and-quotas-in-the-practice-of-pharmacy-resolution-109-7-13/.

the Model Act to address the regulation, restriction, or prohibition of the use of such performance metrics or quotas.

NABP's resolution also resulted in a request to the Institute for Safe Medication Practices (ISMP) to study the effect of performance metrics on patient care. ISMP is recognized for its medication safety information and worked with a number of boards of pharmacy to develop quality control standards and regulations. ISMP's advocacy work has resulted in numerous necessary changes in clinical practice, public policy, and drug labeling and packaging.

ISMP responded to NABP's request by collaborating with the American Pharmacist Association (APhA) and surveying community pharmacists, "The Community Pharmacy Time Guarantee Survey." Of the 673 community pharmacists who responded to the survey, 83% stated that they believed that distractions due to performance metrics or measure wait time contributed to dispensing errors and that 49% felt specific time measurements were a significant contributing factor. Most of the ISMP survey respondents worked in a chain pharmacy (45%). Based on the survey results, ISMP stated that "the severity of the problem and the intensity of sentiments from pharmacists who work within such an environment call for a more in-depth exploration of the issue and discussion regarding how time guarantees impact patient safety and diminish the role of pharmacists in all practice settings."[439] In 2008, and again in 2011, ISMP warned that prescription guarantee times "jeopardize public health by discouraging pharmacists from spending time checking the patient's history and drug profile; checking for drug interactions, duplications, or other drug use evaluation concerns; calling physicians' offices for clarification; educating patients about the proper use of prescriptions; or any other critical function that promotes safety."[440]

NABP's 2013 Resolution also found that performance metrics, which measure the speed and efficiency of prescription workflow by such parameters as prescription wait times, percentage of prescriptions filled within a specified time period, number of prescriptions verified, and the number of immunizations given per pharmacist shift, "may distract pharmacists and impair professional judgment." In addition, NABP found that the practice of applying performance metrics or quotas to pharmacists "may cause distractions that could potentially decrease pharmacists' ability to perform drug utilization review, interact with patients, and maintain attention to detail, which could ultimately lead to unsafe conditions in the pharmacy."

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[439] Institute for Safe Medication Practices, Prescription Drug Time Guarantees and Their Impact on Patient Safety in Community Pharmacies. *ISMP Medication Safety Alert!* 2012 Sep; 18(17):1-4.
[440] Institute for Safe Medication Practices, Speed trap. *ISMP Medication Safety Alert! Community/Ambulatory Care Edition* 2008 Oct; 7(10):2-3 Institute for Safe Medication Practices, Return of the speed trap. *ISMP Medication Safety Alert! Community/Ambulatory Care Edition* 2011 Mar; 10(3):1.

In 2018, the House of Delegates of the American Pharmacist Association (APhA), the nation's oldest and largest professional organizations of pharmacists, adopted the "Pharmacy Workplace Environment and Patient Safety" policy.[441] The policy states that APhA "opposes the setting and use of operational quotas or time-oriented metrics that negatively impact patient care and safety." Rather than impose performance metrics, APhA "supports staffing models that promote safe provision of patient care services and access to medications" and "encourages the adoption of patient-centered quality and performance measures that align with safe delivery of patient care services . . .."

The National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP), also passed a statement advocating for the "elimination of prescription time guarantees and a strengthened focus on the clinical and safety activities of pharmacist within the community pharmacy setting."[442] "The Council believes prescription time guarantees and inducements . . . can be detrimental to patient safety. Forcing pharmacists to work quickly has the potential to lead to the development of at-risk behaviors that can rapidly become unsafe practice habits . . .. the added time pressures may discourage pharmacists from conducting critical clinical and safety checks which can result in medication errors."

In 2016, I assisted with the development and execution of a two-year investigative study and resulting series of articles by the Chicago Tribune. The study involved the presentation of two prescriptions for drugs that should not be dispensed together to a representative sample of community pharmacies across the State of Illinois. The study found that "pharmacies miss more than half of dangerous drug combinations on drug-drug interactions." The study and articles identified 255 pharmacies, including the retail pharmacy defendants. I was involved in all phases of the study including the overall design, selection of drugs for the drug-drug interaction, selection and training of "pharmacy shoppers," and the collection and analysis of data.

The report found that 52 percent of the pharmacies dispensed the medication without mentioning the potential interactions. CVS had the highest failure rate among the Chain Pharmacies tests, dispensing the drugs with no warning 63 percent of the time. Wal-Mart failed 43 percent of its tests and Walgreens 30 percent. The report found that "pharmacists frequently race through legally required drug safety reviews — or skip them altogether." "[S]ome pharmacies emphasize fast service over patient safety. Several chain pharmacists, in interviews, described assembly-line conditions in which staff hurried to fill hundreds of prescriptions a day." A Walmart pharmacist

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[441] Actions of the 2018 American Pharmacists Association House of Delegates (March 2018), https://www.pharmacist.com/sites/default/files/files/2018%20Report%20of%20the%20APhA%20House%20of%20Delegates%20-%20FINAL.pdf.

[442] National Coordinating Council for Medication Error Reporting and Prevention. Statement Advocating for the Elimination of Prescription Time Guarantees in Community Pharmacy, http://www.nccmerp.org/statement-advocating-elimination-prescription-time-guarantees-community-pharmacy.

commented that she "typically fills 200 prescriptions in her daily nine-hour shift," and an even higher volume when she worked at a different store, equating to two prescriptions per minute.

The report states that the New Hampshire Board of Pharmacy sampled data from two retail chains in the state and found that pharmacists spend an average of 80 seconds on safety checks for each prescription filled. The president of the Board, Bob Stout, explained: "They're cutting corners where they think they can cut." "What happens, I found on the board, is people stop doing (safety) reviews." "They're not going in looking at patient records."

In response to the report, Thomas E. Menighan, the head of APhA, wrote "performance metrics that pressure pharmacists to work quickly" "contribute to a great deal of stress that can result in unintended patient harm."[443] A recent New York Times report discussed pharmacists who said, "the focus on metrics was a threat to patient safety" and "[m]etrics put unnecessary pressure on pharmacy staff to fill prescriptions as fast as possible, resulting in errors."[444]

A pharmacist pressured to work too quickly who misses dangerous drug interactions and does not have sufficient time to perform safety reviews is likewise at risk of missing red flags of diversion, including, for example, drug "cocktails" or other combinations of highly abused drugs described above. The high stress and chaotic environment created by arbitrary performance metrics is exacerbated by inadequate staffing at the Chain Pharmacies. Unreasonable volume and speed demands on pharmacists coupled with too little staff means pharmacists cannot properly review prescriptions to ensure their appropriateness and validity and resolve any red flags.

The New York Times report stated that "[i]n letters to state regulatory boards and in interviews with The New York Times, many pharmacists at companies like CVS, Rite Aid and Walgreens described understaffed and chaotic workplaces where they said it had become difficult to perform their jobs safely. . .."[445] Documents with survey responses reviewed in this case also show many pharmacy employees reported that too little staff affected their ability to ensure patient safety.[446]

State boards of pharmacy also reported receiving complaints from pharmacists regarding workload, pharmacist and technician support, and performance metrics. The Oregon Board of Pharmacy surveyed pharmacists in 2012. The 1,300 responses identified workloads, distractions, and services designed to augment profits as major items of concern. Around the same time, the

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[443] Pharmacists Provide Care, *Fighting to let pharmacists keep patients safe*, APhA, https://pharmacistsprovidecare.com/CEOBlog/fighting-let-pharmacists-keep-patients-safe.
[444] Ellen Gabler, *How Chaos at Chain Pharmacies is Putting Patients at Risk*, New York Times, Jan. 31, 2020, https://www.nytimes.com/2020/01/31/health/pharmacists-medication-errors.html.
[445] *Id.*
[446] WMT_MDL_000976998; WMT_MDL_000661952 - WMT_MDL_000661981;

Iowa and North Carolina Boards of Pharmacy also examined the impact of the pharmacist workplace on patient care and medication errors. Most recently, the Ohio and California Boards of Pharmacy conducted and decided to conduct, respectively, surveys of pharmacists licensed by their boards. The Ohio Board of Pharmacy noted in its survey that, "Capturing this data is important as pharmacist working conditions have been identified as a concern among licensees, state regulators (several of which have issued similar surveys) and national organizations."[447]

The Defendants also tie pharmacist bonuses and other financial incentives to the number of prescriptions filled, including prescriptions for controlled substances. The added direct impact on salary and bonus if metrics were not met further overrode pharmacists' professional judgment and legal responsibilities.

In 2013, the DEA expressed concerns that bonus incentives for dispensing controlled substances could "lead to bad pharmacist decisions because they know they get will something out of filling scripts."[448] Walmart "agree[d]" with the DEA's concerns "that there should be no special incentives for filling controlled substance prescriptions" but then does not appear to have excluded controlled substance prescriptions from bonus calculation formulas.[449]

K. Summary

This opinion is based upon my review of information, data, and considerations presented for my review, experience and expertise in the practice and regulation of pharmacy, and the usual and customary practice of pharmacy and pharmacy practices. It is my opinion that the Defendants and their pharmacists held, and continue to hold, a corresponding responsibility to only fill prescriptions for controlled substances that are issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his/her professional practice. Based on my review of the policies and procedures instituted by the Defendants governing pharmacy operations, Defendants' pharmacists abilities to carry out their corresponding responsibility obligations were significantly impacted. Further, Defendants failed to provide their pharmacists with the data and tools necessary to fulfill their corresponding responsibility duties, including but not limited to, providing their pharmacists with access to dispensing data as well as the analysis of that data as it relates to red flags of diversion. The failure to provide such data resulted in significant quantities

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[447] State of Ohio, Board of Pharmacy, Pharmacist Workload Survey, April 2021. https://www.aacp.org/article/2019-national-pharmacist-workforce-study

[448] WMT_MDL_000233226 (NACDS DEA Compliance Working Group Meeting Summary (Feb. 12, 2013).

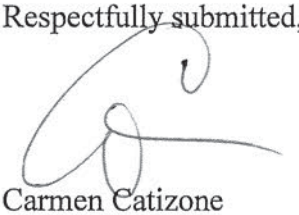
[449] WMT_MDL_000361054 - WMT_MDL_000361069; WMT_MDL_000891159.

of controlled substances, particularly opioids, being dispersed outside of the closed distribution and dispensing system.

Corporate oversight includes established practices of pharmacies that should incorporate top-down compliance programs using data readily available to the corporation to guard against diversion. Corporate oversight should set patient care and integrity expectations and provide tools for pharmacists to exercise best practices to adhere to appropriate laws, regulations, and pharmacy standards of care in dispensing controlled substances. The report examined Defendants' actions with respect to maintaining effective policies and practices to guard against the diversion of prescription opioids, provision of important information and data to pharmacists in their pharmacies, well-established pharmacy standards of care, and the dispensing of opioids into Lake and Trumbull Counties despite obvious and significant red flags.

Defendants were and remain aware of these requirements. Defendants delayed implementing controlled substance diversion policies and when implemented, failed to monitor and enforce effective policies and procedures to guard against diversion. Instead, Defendants implemented and enforced employment evaluation policies and performance metrics that impeded their pharmacists' efforts to comply with laws and regulations and meet standards of care. The Defendants' actions and failure to meet their corresponding responsibilities caused Defendants' pharmacies to fill thousands of prescriptions presenting significant red flags without evidence of resolving those red flags prior to dispensing and causing a failure to maintain effective controls to guard against diversion which resulted in significant public harm and injury.

Respectfully submitted,



Carmen Catizone

Executed on May 19, 2021

CURRICULUM VITAE
CARMEN A CATIZONE, MS, RPH, DPH
Arlington Heights, Illinois

CARMEN A CATIZONE,
Pharmacist, MS, RPH, DPH

CURRICULUM VITAE

Biography:

Mr Catizone currently is a Senior Advisor to the National Association of Boards of Pharmacy® (NABP®) after serving 35 years as the Association's Tests and Measurements Director and Executive Director. NABP is an international organization whose membership includes the state boards of pharmacy in all 50 United States, the District of Columbia, Guam, Puerto Rico, the Virgin Islands, Bahamas, and Provincial pharmacy regulating agencies in Canada.

Mr Catizone is also a Founding Partner of Catizone. Luce, and Menighan Pharmacy Advisors (CLM) a consulting practice specializing in pharmacy practice, regulation, and supply chain integrity. CLM assists clients anticipate and navigate change to in the pharmacy environment and proactively identify regulatory requirements to support effective and compliant practice models.

Mr Catizone graduated from the University of Illinois at Chicago, College of Pharmacy, with a Bachelor of Science degree in pharmacy and a Master of Science degree in pharmacy administration. He served as a Governor of the Pharmacy Technician Certification Board (PTCB) Board of Directors and Chair of the PTCB Certification Council; a Past President of the National Pharmacy Manpower Project and the National Conference of Pharmaceutical Organizations (NCPO); as well as a Trustee of the United States Pharmacopeia (USP) Board of Directors. He is a reviewer on several advisory boards and provides expert witness testimony and consultation in the areas of pharmacy practice and regulation for the Drug Enforcement Administration (DEA) and US Attorneys' Offices across the US.

Mr Catizone is the recipient of many honors and awards including an Honorary Doctor of Pharmacy, the Certificate of Appreciation from the District of Columbia, two Food and Drug Administration (FDA) Commissioner Special Citations, the Federation of State Medical Boards Award of Merit, the National Council of State Boards of Nursing (NCSBN) Founders' Award, the University of Illinois Alumnus of the Year, and American Druggist Magazine Pharmacist of the Year.

Education:

Master of Science, University of Illinois at Chicago, Graduate College, Pharmacy.

Bachelor of Science, University of Illinois at Chicago, College of Pharmacy.

Licenses:

Honorary Doctor of Pharmacy, Oklahoma State Board of Pharmacy.

Registered Pharmacist, Illinois.

CURRICULUM VITAE
CARMEN A CATIZONE, MS, RPH, DPH
Arlington Heights, Illinois

Experience

Catizone, Luce, & Menighan – CLM Pharmacy Advisors

Founding Partner
CLM Pharmacy Advisors specializes in pharmacy regulatory matters (state boards of pharmacy, DEA, FDA), operational guidance, and strategic planning. CLM offers over 100 years of experience in the pharmacy environment providing clients with the strategic and operational assistance needed to shift compliance and operations from reactive to proactive with consideration of essential elements such as risk management, risk mitigation, and enterprise-wide solutions.

National Association of Boards of Pharmacy (NABP)

Senior Advisor May 2020 – Present
Provides advice and counsel to NABP's Executive Committee and senior staff on all matter and operations of the Association.

Executive Director/CEO, 1988-May 2020
Responsible to the Executive Committee (Board of Directors) of the Association for the oversight of the NABP staff and design, delivery and quality of programs, products and services offered by NABP. Also responsible for assisting the Executive Committee to fulfill its governance functions as well as provide direction and leadership toward the achievement of the NABP philosophy, mission, and strategic plan. Liaison with all state and federal agencies on behalf of the Association and chief spokesperson.

Tests and Measurement Director, 1985-1988
Responsible for the National Association of Boards of Pharmacy Licensure Examination (NABPLEX), all competence assessment programs and activities of NABP, including at the time, the Federal Drug Law Examination (FDLE) and the Foreign Pharmacy Graduate Equivalency Certification (FPGEC) program.

Registered Pharmacist, Illinois
Practiced in community, hospital, and institutional settings as a registered pharmacist.

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Arlington Heights, Illinois

Presentations:

The Response of US State Regulatory Agencies to COVID-19. FIP Forum of Pharmacy Professional Regulators' Meeting, September 9, 2020, Seville, Spain (Virtual).

Law or Lawless – The Future of Pharmacy Regulation, Keynote Address at American Society for Pharmacy Law Developments in Pharmacy Law Seminar XXX, November 8, 2019, San Diego, California.

Standard of Care Regulatory Approach, Presentation at Virginia Board of Pharmacy Retreat, April 16, 2019, Charles City, Virginia.

NAPLEX and MPJE – The Psychometrics Behind the Exams – Security and Accountability by NABP, NABP/AACP Districts 1 & 2 Meeting Keynote Address presented by Carmen Catizone and Andrew Dedes, September 15, 2017, Groton, Connecticut.

Patient Safety and the Importation of Prescription Drugs, Presentation at the Alliance for Safe Online Pharmacies, May 31, 2017, Washington, DC.

The Case Against Prescription Drug Importation, Risking Safety at All Costs: How Drug Importation is Dangerous Policy, Presentation/Panel Discussion at the National Press Club, April 4, 2017, Washington, DC.

A Pharmacy Conversation, Panel Discussion at Healthcare Distribution Alliance 2016 Annual Board and Membership Meeting, September 26, 2016, White Sulphur Springs, West Virginia.

Understanding Corresponding Responsibility and Red Flags in Pharmacy Cases, Presentation at DEA Federal Pharmaceutical Drug Investigation and Prosecution Training, August 24, 2016, Addison, Texas.

Keynote Address at Quarles and Brady, LLP 2016 Pharmacy Law Symposium, July 21, 2016, Chicago, Illinois.

National Tri-Regulatory Collaborative, Presentation at Minnesota Tri-Regulatory Symposium, June 1, 2016, Minneapolis, Minnesota.

Regulation Versus Technology / Health Care Across Borders, Session 1: Health Professional Regulation and Trade Agreements – Protecting the Public Versus Facilitating Commerce, Presentation/Panel Discussion at World Health Professions Regulation Conference 2016, May 21, 2016, Geneva, Switzerland.

Presentation at Nebraska PMP Strategic Planning Meeting, January 21, 2016, Omaha, Nebraska.

Results from the State Survey, FDA Inter-governmental Working Meeting on Drug Compounding, November 16, 2015, Silver Spring, Maryland.

Ensuring Practitioner Competence: Evolving Regulatory and Education Changes, Panel Discussion at ACPE CE Stakeholders Conference, October 30, 2015, Chicago, Illinois.

Assessment in Pharmacy Education, Panel Discussion/Presentation at NABP/AACP District 6,7,8 Meeting, September 16, 2015, Lake Tahoe, Nevada.

Stakeholder Consensus Report – Industries Due Diligence, DEA Diversion Management Training, August 25, 2015, Indianapolis, Indiana.

Sterile Compounding: How applications, enforcement and training are being handled in a post-NECC regulatory climate, NABP/AACP District 3 Meeting, August 17, 2015, St. Augustine, Florida.

New NAPLEX Blueprint – Update on Pharmacy Curriculum Outcomes Assessment, NABP/AACP District 5 Meeting, August 7, 2015, Fargo, North Dakota.

The National Heroin Task Force Subcommittee Meeting, June 18, 2015, Washington, DC.

Implementation of the Memorandum of Understanding, International Academy of Compounding Pharmacists, IACP 21st Annual Compounders on Capitol Hill, June 8, 2015, Washington DC.

Future of Controlled Substances, American Association of Dental Boards Mid-Year Meeting, April 27, 2015, Chicago, Illinois.

S*takeholder Consensus Report*, DEA Distributor Conference, April 15, 2015, National Harbor, Maryland.

Draft Standard Memorandum of Understanding between FDA and the States, FDA Inter-Governmental Working Meeting on Drug Compounding, March 18, 2015, Silver Spring, Maryland.

Secure Drug Distribution in the US and .Pharmacy, Pharmaceutical Trade Marks Group (PTMG) Conference, October 9, 2014, Chicago, Illinois.

Keynote Speaker Remarks, White Coat Ceremony, Fourth Incoming Class, Roosevelt University College of Pharmacy, September 11, 2014, Schaumburg, Illinois.

NABP Regulatory Affairs Update, NABP/AACP District 5 Meeting, August 15, 2014, Deadwood, South Dakota.

An Introduction to Red Flags Video by Carmen A. Catizone MS, RPh, DPh, developed by the Anti-Diversion Industry Working Group (ADIWG) and NABP for the AWARxE Prescription Drug Safety Program, NABP 110th Annual Meeting, May 20, 2014, Phoenix, Arizona.

Compounding Session, Moderators: Carmen A. Catizone, MS, RPh, DPh and Karen M. Ryle, MS, RPh, NABP President, NABP 110th Annual Meeting, May 19, 2014, Phoenix, Arizona.

Controlled Substances Oversight and Prescription Drug Abuse, MPA Pharmacy Law and Policy Symposium, Michigan Pharmacy Association, April 23, 2014, Lansing, Michigan.

Co-Regulating Interstate Distribution of Compounded Drugs pursuant to Section 503A under a Memorandum of Understanding (MOU) with FDA, FDA Federal-State Meeting on Pharmacy Compounding, March 20, 2014, Silver Spring, Maryland.

The Challenges of Prescription Drug Abuse, American Medical Association Corporate Roundtable Discussion, March 5, 2014, Washington, DC.

Prescription Opioid Abuse, Misuse and Diversion, Tri-Regulator Collaborative Boards of Directors Meeting (Federation of State Medical Boards/National Association of Boards of Pharmacy/National Council of State Boards of Nursing), February 5, 2014, Dallas, Texas.

A Look Forward on Regulation - What's Next? An Eye Toward Portability, The Federation of Associations of Regulatory Boards (FARB) Forum, January 24, 2014, Austin, Texas.

Rogue Internet Pharmacies, NABP/AACP Districts 1 & 2 Meeting, October 19, 2013, Bar Harbor, Maine.

Understanding the Regulatory Landscape: Compounding Tragedy Lessons Learned, CLEAR

Conference, October 3, 2013, Springfield, Missouri.

Compounding the Situation, NABP/AACP Districts 6, 7, 8 Meeting, September 11, 2013, Boulder, Colorado.

Current Issues in the Regulation of Internet Pharmacies, FIP World Congress Meeting, September 2, 2013, Dublin, Ireland.

.*Pharmacy Generic Top-Level Domain Initiative and Internet Drug Outlet Identification Program – Report on Investigation and Related Outcomes – Update*, NABP/AACP District 5 Meeting, August 9, 2013, Winnipeg, Manitoba Canada.

New Technology to Prevent Drug Diversion and Drug Administration Errors, Conference of Western Attorneys General (CWAG) Annual Meeting, July 22, 2013, Colorado Springs, Colorado.

Overview of NABP Programs and Services, Illinois State Board of Pharmacy Meeting, July 9, 2013, Chicago, Illinois *Update on Pharmacy Issues*, Indian Health Service (IHS) Southwest Regional Pharmacy Continuing Education Meeting, May 4, 2013, Scottsdale, Arizona.

Understanding the Regulatory Landscape, March in the Midwest: A State Government Relations Workshop, Quarles & Brady LLP, March 22, 2013, Chicago, Illinois.

Compounding: From Concern to Safe Patient Care, APhA Annual Meeting, March 3, 2013, Los Angeles, California.

DEA Training Academy for DEA Diversion Investigation Training Course #17, January 15, 2013, Quantico, Virginia.

NABP to Inspect Compounding Pharmacies, ASHP Midyear Clinical Meeting, December 5, 2012, Las Vegas, Nevada.

Perspectives from NABP, HDMA Annual Board & Membership Meeting, October 2, 2012, Palm Beach, Florida.

Telemedicine/Telepharmacy: Practice Models and Regulatory Landscape, Pharmacy Leaders Forum, September 28, 2012, Greensboro, North Carolina.

Community Pharmacy Practice Accreditation, NABP/AACP District 3 Meeting, August 13, 2012, Savannah, Georgia.

Community Pharmacy Practice Accreditation, NABP/AACP District 5 Meeting, August 4, 2012, Duluth, Minnesota.

Presentation on PARE (Pharmacist Assessment for Remediation Evaluation), California State Board of Pharmacy, July 18, 2012, Sacramento, California.

Expanding Pharmacists' Scope of Practice: Challenges, Successes and Opportunities, University of California at San Francisco, Health Policy for Pharmacists Course Lecture, May 7, 2012, San Francisco, California.

Emerging Regulatory Issues, American Pharmacists Association Annual Meeting, National Initiative Panel Discussion, March 9, 2012, New Orleans, Louisiana.

Practice Advancement: Resources & Training Issues, NABP/AACP District 4 Meeting, November 11, 2011, Findlay, Ohio.

Opening and Welcome Greetings, NABP/AACP District 6,7,8 Meeting, October 5, 2011, Seattle, Washington.

Pfizer Inc., Participant in Pfizer Media Anti-Counterfeit Campaign, Satellite/Radio Tour, September 28, 2011, New York, New York.

Pharmacy Accreditation – Challenge and Opportunity, NABP/AACP District 3 Meeting, August 8, 2011, Biloxi, Mississippi.

Pharmacy Accreditation – Challenge and Opportunity, NABP/AACP District 5 Meeting, August 6, 2011, Saskatoon, Saskatchewan, Canada.

Prescription Drug Monitoring Programs –Interconnect PMPi Project Update, NABP/AACP District 5 Meeting, August 5, 2011, Saskatoon, Saskatchewan, Canada.

The Assessment Program Developed by the National Association of Boards of Pharmacy, Citizen Advocacy Center, June 22, 2011, Washington, DC.

DEA Diversion Investigative Training Course #13, DEA Training Academy, Diversion Investigations School #14, May 10, 2011, Quantico, Virginia.

Pfizer Inc., Consultant in Pfizer Anti-Counterfeit Initiative Video Series, May 4, 2011, New York, New York.

National Pharmacy Focus: NCPA and NABP Leaders Speak, Ohio Pharmacists Association, 133rd Annual Conference and Trade Show, April 18, 2011, Columbus, Ohio.

Contemporary Pharmacy Practice . . . Assuring Public Health and Safety, Midwestern University, College of Pharmacy, February 11, 2011, Downers Grove, Illinois.

DEA Diversion Investigative Training Course #1, DEA Training Academy, Diversion Investigations School #13, February 10, 2011, Quantico, Virginia.

Quality of Care: Can Pharmacy Measure Up?, Sebok Lecture at Ohio Northern University, January 18, 2011, Ada, Ohio.

DEA Diversion Investigative Training Course #1, Drug Enforcement Administration Training Academy, January 28, 2010, Quantico, Virginia.

Regulatory Issues in Pain Management - ASCP 40th Annual Meeting and Exhibition, November 18, 2009, Anaheim, California.

Regulation of Pharmacy Practice – Yes, the Pharmacist is Responsible! – Drug Enforcement Administration, Diversion Operations Unit (TRDD), August 13, 2009, Houston, Texas.

Food and Drug Administration (FDA)/Center for Drug Evaluation and Research (CDER) Open Public Hearing Session, Acetaminophen Forum, University of Maryland, Joint Meeting of the Drug Safety and Risk Management Advisory Committee with the Anesthetic and Life Support Drugs Advisory Committee and the Nonprescription Drugs Advisory Committee, June 30, 2009, Adelphi, Maryland.

Boyle, M and Catizone C A, University of Illinois at Chicago College of Pharmacy, Third Professional

Year Pharmacy Students, March 5, 2009, Chicago, Illinois.
Boyle, M and Catizone C A, *NABP Contemporary Pharmacy Practice…Assuring Public Health and Safety*, Lecture to Pharmacy Law and Ethics Midwestern University Chicago College of Pharmacy Third Year Pharmacy Students, February 20, 2009, Downers Grove, Illinois.

Developing Partnerships: Safety Net Clinics and State Boards of Pharmacy, University of Southern California School of Pharmacy in collaboration with the Department of Health and Human Services Health Resources and Services Administration's Patient Safety & Clinical Pharmacy Services Collaborative, February 12, 2009, Los Angeles, California.

Internet Pharmacy - The Good, The Bad and The Ugly, Drug Enforcement Agency Training Academy, February 3, 2009, Quantico, Virginia.

Internet Pharmacy Practice NABP® Perspective, NABP®/AACP District 1/District 2 Annual Meeting, October 16-18, 2008, Galloway, New Jersey.

Internet Pharmacy Practice NABP® Perspective, NABP®/AACP District 6/District 7/District 8 Annual Meeting, September 17-19, 2008, Park City, Utah.

Maine, Lucinda and Catizone, C A, *When Pharmacy Boards and Educators Collaborate,* Keynote Address at NABP®/AACP District 3 Annual Meeting, August 17–19, 2008, Sand.estin, Florida.

Overview of Pharmacy Curriculum Outcomes and Assessment (PCOA) and NABP®'s Perspectives, NABP®/AACP District 5 Annual Meeting, August 7–9, 2008, Fargo, North Dakota.

Newton, D W, Boyle, M, Catizone, C A, The NAPLEX: Evolution, Purpose, Scope, and Educational Implications, AACP 2008 Annual Meeting, July 21, 2008, Chicago, Illinois.

Pharmacy Perspective Presentation: Regulation of Pharmacy Practice – Yes, the Pharmacist is Responsible! - National Advocacy Center Internet Drug Diversion Seminar, May 29, 2008, Columbia, South Carolina.

Boyle, M and Catizone C A, University of Illinois at Chicago College of Pharmacy, Third Professional Year Pharmacy Students, March 6, 2008, Chicago, Illinois.

Boyle, M and Catizone C A, Pharmacy Law and Ethics Midwestern University Chicago College of Pharmacy Third Year Pharmacy Students, February 15, 2008, Chicago, Illinois.

Catizone, C A and Zweber, Ann, *Pharmacy's Role in Facilitating a New Vision,* NABP®/AACP District 7 and District 8 Annual Meeting, October 3–6, 2007, Ashland, Oregon.

Catizone, C A, McKenzie, Michael (for William Riffee) and Vlasses, Peter, *E-learning & International Programs– Working with Regulatory Agencies:* NABP®/AACP District 3 Annual Meeting, August 6, 2007, Lake Buena Vista, Florida.

Boyle, M and Catizone C A, University of Illinois at Chicago College of Pharmacy, Third Professional Year Pharmacy Students, March 8, 2007, Chicago, Illinois.

Wholesale Licensure requirements: The Path of the Pedigree: Georgia Pharmacy Association 2006 Annual Policy Conference, September 19, 2006, Washington, DC.

Commencement Address: Mercer University Southern School of Pharmacy, May 6, 2006, Atlanta, Georgia.

University of Illinois at Chicago College of Pharmacy, Professional Development Students, February 21, 2006, Chicago, Illinois.

VAWD: Healthcare Distribution Management Association (HDMA) Government Council Meeting, February 16, 2006, Washington, DC.

Food and Drug Administration (FDA) Radiofrequency Identification (RFID) Keynote Remarks: FDA Anti- Counterfeit Drug Initiative Public Workshop & Vendor Display, February 8, 2006, Bethesda, Maryland.

Internet Pharmacies: What Lies Ahead? - 26th Annual Arnold Schwartz Memorial Symposium on Drug Importation and Counterfeiting: How Safe is the Nation's Drug Supply, November 20, 2005, LaGuardia, New York.

National Issues–NABP® Blueprint for 2005-2006: MALTAGON 2005 Meeting, September 15, 2005, Charlotte, Iowa.

Contemporary Pharmacy Practice–Assuring Public Health & Safety States Boards of Pharmacy: University of Iowa College of Pharmacy, April 19, 2005, Iowa City, Iowa.

A Perspective from NABP®: Pharmacist Transition to Become Healthcare Providers: NABP®/AACP District 4 Annual Meeting, November 3, 2004, Columbus, Ohio.

Continuing Professional Development (CPD) in Pharmacy: NABP®'s Vision of CPD: NABP®/AACP District 2 Annual Meeting, October 22, 2004, Chester, West Virginia.

Issues in Medication Importation: 2004 Illinois Pharmacists Annual Conference, September 19, 2004, Arlington Heights, Illinois.

Keynote Address at American Association of Veterinary State Boards, September 17, 2004, Kansas City, Missouri.

CPD: Perspective of the National Association of Boards of Pharmacy: NABP®/AACP District 3 Annual Meeting, August 1, 2004, Biloxi, Mississippi.

Quality Standards and Practice Issues in Pharmacy Compounding–The NABP® Perspective: 2004 Summer Symposium The Pharmacy Law Institute Ohio Northern University Rudolph H. Raabe College of Pharmacy, July 30, 2004, Ada, Ohio.

NABP® Model State Regulations: HDMA Distribution Management Conference, June 17, 2004, Las Vegas, Nevada.

Nevada Commencement Address University of Southern Nevada, June 5, 2004, Henderson, Nevada.

Public Policy Issues: Illegal Importation and Counterfeit Drugs/NABP® Model Rules for the Licensure of Wholesale Distributors: State Efforts to Combat Counterfeit Drugs: Food and Drug Law Institute Conference: "Fakes and Imports: Federal and State Initiatives Concerning Counterfeit Drugs and Reimportation", May 3, 2004, Chicago, Illinois.

E-Pharmacies: Consumer Protection and Regulatory Challenges: National Conference of State Legislatures Spring Forum, April 30, 2004, Washington, DC.

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Public Policy Issues: Illegal Importation and Counterfeit Drugs: American Society of Consultant Pharmacists' 15th Annual Conference on Legislative & Regulatory Affairs, April 5, 2004, Washington, DC.

Ohio Northern University Rudolph H. Raabe College of Pharmacy Third-year Students, March 31, 2004, Ada, Ohio.

Counterfeit Drugs: Drug Information Association's Conference on Combating Counterfeit Drugs, March 17, 2004, Washington, DC.

Assuring Public Health & Safety: The Role of the Boards of Pharmacy in the Twenty-First Century: Iowa Pharmacist Association's Legislative Day Conference, February 17, 2004, Des Moines, Iowa.

Drug Schedule System: National Drug Scheduling Advisory Committee (NDSAC) Meeting, February 15, 2004, Toronto, Ontario, Canada.

Illegal Importation of Prescription Drugs: MALTAGON 2003 Meeting, November 10, 2003, Pine Mountain, Georgia.

NABP® Continuing Professional Development Program: National Council of State Pharmacy Association Executives 2003 Meeting, October 18, 2003, Seattle, Washington.

Efforts of the State Boards of Pharmacy & NABP® to Combat the Threat of Counterfeit Drugs: FDA Public Hearing, October 15, 2003, Bethesda, Maryland.

The Regulatory Evolution of Pharmacy Technicians: National Pharmacy Technician Association Fall Conference, Caremark Rx–Mount Prospect Facility, September 27, 2003, Mount Prospect, Illinois.

Drug Reimportation: Are our Patients in Danger? - NABP®/AACP District 7/District 8 Annual Meeting, September 3-6, 2003, Kalispell, Montana.

Illegal Importation of Prescription Drugs: National Association of Chain Drug Stores (NACDS) 2003 Pharmacy and Technology Conference, August 25, 2003, Philadelphia, Pennsylvania.

Drug Enforcement Agency (DEA) and State Regulatory Developments: HDMA 2003 Conference and Exposition, June 11, 2003, Orlando, Florida.

Internet Pharmacies, Imported Pharmaceuticals, and Regulation: HDMA 2003 Conference and Exposition, June 11, 2003, Orlando, Florida.

Importation of Prescription Drugs from Canada, Food & Drug Law Institute sponsored Audio Conference, April 25, 2003.

Is the NAPLEX® in Our Future?: Legislative Day sponsored by the University of California, San Francisco School of Pharmacy, April 15, 2003, San Francisco, California.

Compounding Update: What is the Future of Compounding? American Society for Pharmacy Law Annual Conference "Developments in Pharmacy Law Seminar XIII", November 1, 2002, Amelia Island, Florida.

Internet Sales Panel: Annual Educational Conference Co-Sponsored by Illinois Environmental Health Association, October 22, 2002, St. Charles, Illinois.

Licensure of Pharmacists in the United States: History, Process and Qualification: Pharmaceutical Society of Japan, Shibuya, Tokyo, Japan, February 28, 2002, Tokyo, Japan.

NACDS HIPAA Conference, February 22, 2002, Chantilly, Virginia.

Internet Pharmacies–VIPPS®: NABP®/AACP District 6 Annual Meeting, October 6, 2001, Little Rock, Arkansas.

Regulating for Pharmaceutical Care Outcomes: NACDS 2000 Pharmacy, Managed Care & Technology Meeting, August 27, 2000, San Diego, California.

VIPPS® or Not to VIPPS®? National Council for Prescription Drug Programs 2000 August Educational Forum, August 20, 2000, Baltimore, Maryland.

Leadership Through Technology: Federation of Association of Regulatory Boards Leadership Conference, July 14, 2000, Chicago, Illinois.

What's New In Pharmacy: Citizens Advocacy Center June Meeting, June 23, 2000, Washington, DC.

Professional Competency: Ohio Northern University Rudolph H. Raabe College of Pharmacy Students, April 26, 2000, Ada, Ohio.

Pharmacy Technician Conference, South Suburban College, March 30, 2000, South Holland, Illinois.

Pharmacy Practice and Regulation: Cooperation and Collaboration: Howard L. Reed Annual Refresher Course and Homecoming, March 9, 2000, Worcester, Massachusetts.

Professional Competence: University of Illinois at Chicago College of Pharmacy Final-year Students, March 6, 2000, Chicago, Illinois.

Internet Pharmacies: Second Annual Canadian Association of Chain Drug Stores Conference, February 9, 2000, Toronto, Ontario, Canada.

Telepharmacy: Issues and Future: American Society of Health-System Pharmacies (ASHP) 34th Mid-year Clinical Meeting, December 5, 1999, Orlando, Florida.

Effective Regulation of Collaborative Practices: Citizen Advocacy Center's 12th Annual Meeting, November 5, 1999, Orlando, Florida.

Workshop Presentation on Cyber Drugstores & the Internet Savvy Consumer: NACDS 1999 Pharmacy Conference and Managed Care Forum, August 30, 1999, San Diego, California.

Internet Pharmacy Program: NACDS 1999 Pharmacy Conference & Managed Care Forum, August 30, 1999, San Diego, California.

NABP® Regulations and Position: National Council for Prescription Drug Programs' 1999 Educational Forum, August 15, 1999, Baltimore, Maryland.

Pharmacists Credentialing: Trends and Implications: 124th Annual Convention of the Georgia Pharmacy Association, June 27, 1999, Asheville, North Carolina.

Pharmacists Credentialing: Trends and Implications: Missouri Pharmacy Association Annual Meeting, June 11, 1999, Osage Beach, Missouri.

Pharmacists Credentialing: Trends and Implications: Food Marketing Institute's 12th Annual Supermarket Pharmacy Conference, April 19, 1999, Baltimore, Maryland.

Disease State Management: Objectives, Standards & Credentialing: New Hampshire PharmAssist Foundation Meeting, April 18, 1999, Bedford, New Hampshire.

Professional Competence: University of Illinois at Chicago, College of Pharmacy Final Year Students, March 12, 1999, Chicago, Illinois.

Role of NABP® in Pharmacist Credentialing: Town Hall on Pharmacists Credentialing Program at the National Community Pharmacists Association's (NCPA) 100th Annual Convention and Trade Exposition, October 21, 1998, St. Louis, Missouri.

Wake Up Call for Pharmacists: First Indiana Pharmacists Alliance Annual Meeting, September 11, 1998, Indianapolis, Indiana.

Confidentiality and Compliance Programs: Are Patient Records Really at Risk? NACDS 41st Annual Meeting, September 2, 1998, San Diego, California.

Competency Testing for Pharmacists–Will It Come Soon? Ohio Pharmacists Association 120th Annual Conference, April 25, 1998, Columbus, Ohio.

Telepharmacy: Ohio Northern University, Rudolph H. Raabe College of Pharmacy Contemporary Pharmacy Practice Class Third-year Students April 15, 1998, Ada, Ohio.

The Licensure Debate: Legal Issues in Homecare Telemedicine Conference sponsored by Legamed® and Advocate Health Care, March 30, 1998, Chicago, Illinois.

New Challenges in the Future of Pharmacy Practice: Drug Enforcement Administration's Eighth National Conference on the Control and Diversion of Controlled Substances and Chemicals, March 26, 1998, Denver, Colorado.

Continuing Competence and Self-Assessment: Issues for Pharmacists and the Public: Federal Service Forum at the ASHP's Mid-year Clinical Meeting, December 7, 1997, Atlanta, Georgia.

What to Expect From Your Pharmacist: Operation Medication Awareness for Seniors, Morris-Sussex Society of Pharmacists, Birchwood Manor, October 15, 1997, Whippany, New Jersey.

The Development and Implementation of the Pharmacist Continued Competence Assessment Mechanism (PCCAM): Competency Testing Retreat, Pharmacy Coordinating Council of Utah, University of Utah College of Pharmacy, September 18, 1997, Salt Lake City, Utah.

Update from the National Association of Boards of Pharmacy: 26th Annual Pharmacy Law and Management Conference, September 13-14, 1997, Orlando, Florida.

Compounding: Laboratory Instructors Special Interest Group at AACP, July 15, 1997, Indianapolis, Indiana.

Competency: 1997 Pharmacy Conference, May 4, 1997, Auckland, New Zealand.

The State Perspective: 18th Annual Northeast Pharmaceutical Conference, April 10, 1997, Philadelphia,

Pennsylvania. Klein, Lawrence W and Catizone, C A, *Validation of the Blueprint for an International Licensure*

Examination:
Paper (23 p) presentation, National Council on Measurement in Education Annual Meeting, March 25–27, 1997, Chicago, Illinois.

Regulatory Issues for Today and Tomorrow: Iowa Pharmacists Association "Legislative Day," March 5, 1997, Des Moines, Iowa.

Future National Regulatory Issues: MALTA–GO Conference, November 9, 1996, Savannah, Georgia.

OBRA '90 and its Illinois Law Successor: University of Illinois at Chicago College of Pharmacy PMAD 300 Students, Chicago, Illinois.

Electronic Prescribing: What are the Current Issues? Academy of Managed Care Pharmacy's Linkages for Quality: Information Management for Managed Care Pharmacy Meeting, September 16, 1996, Chicago, Illinois.

Equitable Degree Upgrade Mechanisms for BS Pharmacists: National Pharmaceutical Association, Inc Conference, August 7, 1996, Chicago, Illinois.

The Regulation of Pharmacy Technicians: Certification vs. Registration: American Association of Pharmacy Technicians National Convention '96, August 2, 1996, Bloomington, Minnesota.

Pharmacy Perspective–Session II–"Getting the Point"–Issues of Unsafe Syringe Disposal: Center for Disease Meeting on Workshop on Safe Syringe and Needle Disposal, John Hopkins University, June 20, 1996, Baltimore, Maryland.

Board of Pharmacy Regulations in Home Care: Current & Future Trends: Presentation on the Joint Commission Accreditation of Hospital Organization (JCAHO) Home Care Standards–Problematic Areas & Future Trends at ASHP 30th Annual Mid-year Clinical Meeting, December 4, 1995, Las Vegas, Nevada.

Electronic Transmission of Prescription and Patient Confidentiality Concerns: MALTA–GO Annual Meeting, October 27, 1995, Eureka Springs, Arkansas.

Licensing: National Congress of Pharmaceutical Sciences Licensing & Certification International Meeting of Pharmaceutical Education, Symposium on Accreditation, October 23, 1995, Merida, Yucatan, Mexico.

Pharmacy Issues of the Day: Illinois Pharmacists Association 115th Annual Meeting, September 17, 1995, Itasca, Illinois.

NABP® and State Board Activities: Food Marketing Institute Pharmacy Services & Conference Planning Committee Meeting, September 14, 1995, Chicago, Illinois.

Pharmaceutical Care–Boards of Pharmacy: Glaxo Straight Talk on Emerging Health Care Systems Conference, May 22, 1995, Research Triangle Park, North Carolina.

The NABP® Patient Counseling Survey–Are Pharmacists Communicating With Their Patients?: National

Council on Patient Information and Education National Conference on Prescription Medicine Information and Education, May 8, 1995, Washington, DC.

How OBRA '90 Counseling Requirements Had Their Intended Effect?: Ohio Northern University Rudolph H. Raabe College of Pharmacy Students, April 5, 1995, Ada, Ohio.

The NABP® Workload Study: University of North Carolina at Chapel Hill Annual Socio-Economic Seminar, March 14, 1995, Greensboro, North Carolina.

How Are the State Boards of Pharmacy Regulating OBRA '90: 15th Annual Arnold Schwartz Memorial Program, November 20, 1994, East Elmhurst, New York.

OBRA '90 and Afterwards for the Profession: , University of Illinois at Chicago College of Pharmacy Roles & Environmental Course Students, October 20, 1994, Chicago, Illinois.

Manufacturing Vs. Compounding: Chicago College of Pharmacy Contemporary Compounding Course Third Year Pharmacy Students, September 26, 1994, Downers Grove, Illinois.

Cross Border Agreement: NABP®/AACP District 5 Annual Meeting, August 19, 1994, Winnipeg, Manitoba, Canada.

Model Act: Tri-State Boards of Pharmacy Invitational Conference, Philadelphia College of Pharmacy, April 30, 1994, Philadelphia, Pennsylvania.

PDMA Licensing Issues–The State Perspective: International Narcotics Enforcement Officers Association Pharmaceutical Conference, November 17, 1993, West Palm Beach, Florida

OBRA '90 Provisions: University of Illinois at Chicago College of Pharmacy PMAD 300 Pharmacy Roles and Environment Year One Students, October 14, 1993, Chicago, Illinois.

Impact of Technology on Regulation of Pharmacy: NABP®/AACP District 1 Annual Meeting, October l, 1993, Newport, Rhode Island.

NABP®: Association of Indiana Pharmacists Open Forum Meeting, August 15, 1993, Willowbrook, Illinois.

Patient Counseling Standards: A Challenge For The Profession: Ohio Northern University Rudolph H. Raabe College of Pharmacy, Pharmacy Law Institute Summer Symposium, July 30, 1993, Ada, Ohio.

Proposals in Health Care Reform: Information for Consumers: Drug Information Association 29th Annual Meeting, July 15, 1993, Chicago, Illinois.

The OBRA '90 Patient: New Skills for Counseling and DUR: Challenges of Healthcare Reform: a Rap Meeting presented by the Academy of Managed Care Pharmacy, Texas Pharmaceutical Association, and the Texas Pharmacy Foundation, April 25, 1993, Irving, Texas.

Patient Counseling Standards: A Challenge for the Profession: 38th Annual Ohio Pharmaceutical Seminar, April 20, 1993, Columbus, Ohio.

Board of Pharmacy Role Under OBRA: NABP®/AACP District 6 Annual Meeting, October 17, 1992, Austin, Texas.

Pharmaceutical Care: Is It a Myth or a Possibility?: 4th Annual Focus on Illinois Clinicians

Conference, October 6, 1992, Oak Brook, Illinois.

The North American Free Trade Agreement: Practical Applications and Problems: Council on Licensure, Enforcement and Regulation 12th Annual Meeting, September 23, 1992, Detroit, Michigan.

OBRA '90 The Legal Implications and How To's of Implementation: NACDS, September 2, 1992, Chicago, Illinois.

Brushwood, David B, Catizone, C A, and Coster, John M, *OBRA '90: What It Means To Your Practice*, July, 1992

Pharmacy Care–The Role of Regulation: Iowa Pharmacists Association Annual Meeting, June 20, 1992, Okoboji, Iowa.

R*eview of NABP®'s Model Pharmacy Practice Act:* Georgia Pharmaceutical Association, Inc, June 15, 1992, Savannah, Georgia.

History and Overview of NABP®'s Model Rules: Advisory Committee on the Patient Counseling Requirements of OBRA '90 of the Texas State Board of Pharmacy, June 10, 1992, Austin, Texas.

Compounding Prescriptions & Manufacturing Pharmaceutical Products: NABP® & FDA Perspectives: American College of Apothecaries 1992 Mid-year Conference, May 28, 1992, New Orleans, Louisiana.

Implementing OBRA '90: Food Marketing Institute's 1992 Supermarket Pharmacy Conference, April 13, 1992, Coronado, California.

NABP®'s Wholesale Distributor Clearinghouse: NWDA Government Affairs Committee, April 8, 1992, Alexandria, Virginia.

Regulation of Pharmacy Practice: Issues and Trends: USP Committee of Revision and Board of Trustees, March 20, 1992, Rockville, Maryland.

NABP®'s Model State Pharmacy Practice Act: University of Illinois at Chicago College of Pharmacy, Pharmacy Students, March 5, 1992, Chicago, Illinois.

DUR Report from NABP®: Third American Drug Utilization Symposium, February 21, 1992, San Antonio, Texas.

NABP®'s Recent Initiatives to Pharmacy Practice: University of Illinois College of Pharmacy PMAD 300 Pharmacy Roles and Environment Year One Students, November 4, 1991, Chicago, Illinois.

The Public Expectations of the Pharmacy Practice: Panelist at NABP®/AACP District 2 Annual Meeting, October 25, 1991, Newark, Delaware.

Update: NABP® Model Pharmacy Practice Act: Academy of Managed Care Pharmacy's Partnership to Progress, October 15, 1991, Alexandria, Virginia.

Reactor Comments on Policy Implications of Inappropriate Drug Therapy: 3rd Annual University of Illinois Focus on Illinois Clinicians Conference, University of Illinois at Chicago College of Pharmacy, October l, 1991, Chicago, Illinois.

Prospective DUR–The Role of NABP®: American Drug Utilization Review Symposium sponsored by Searle Inc., September 25, 1991, Nashville, Tennessee.

Reciprocity Trends: 1980–90: NACDS Human Resources Conference, October 14–17, 1990, Phoenix, Arizona.

Standardizing State Internship Requirements: NABP®/AACP District 6 Annual Meeting, October 4–7, 1990, St. Louis, Missouri.

The Faxing of Prescriptions: NABP® 86th Annual Meeting, May 19–23, 1990, Phoenix, Arizona.

Pharmacy Regulations in the 1990's, The NABP® Perspective: NACDS Public Policy Conference, February 14, 1990, Washington, DC.

Statements and Findings From the Pharmaceutical Survey of 1948: NABP®/AACP District 7 Annual Meeting, October 16, 1989, Gleneden, Oregon.

The Prescription Drug Marketing Act of 1987: An Industry Perspective: Pharmaceutical Manufacturers Association's Government Affairs Committee, September 24–27, 1989, Dana Point, California.

Pharmacist Involvement in Research Assessment with Respect to the State Pharmacy Practice Acts: Pharmacist Involvement in Clinical Research: Corporate, Governmental and Regulatory Perspectives Conference, sponsored by the Pharmaceutical & Technological Research Consortium for Ohio, September 6, 1989, Cleveland, Ohio.

NABP®, The Prescription Drug Marketing Act of 1987, and State Licensing of Wholesalers: National Wholesale Druggists' Association Strategic Issue/Legislation Conference, May l, 1989, Washington, DC.

Pharmacy Regulation in the 21st Century: NACDS Pharmacy Affairs Committee Meeting, March 8, 1989, Washington, DC.

The Pharmacist's Duty to Warn: NABP®/AACP District 7/District 8 Annual Meeting, September 10, 1988, Tucson, Arizona.

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Expert Testimony:

United States Attorney (USA):

Trial: Expert Witness USA Office-Eastern District of Michigan, US v. Abiodun Fabode, October 30, 2019.
Matter: Distribution of controlled substances.

Trial: Expert Witness USA Office-Southern District of New York, US v Lena Lasher, May 8, 2015.
Matter: Distribution of prescription drugs over the internet.

Trial: Expert Witness USA Office-Southern District of New York, US v Lee, et al, September 10, 2014.
Matter: Distribution of controlled substances.

Trial: Expert Witness USA Office-Northern District of Ohio, US v Rovedo, et al, October 10, 2012.
Matter: Distribution of controlled substances.

Trial: Expert Witness USA Office-Northern District of California, San Francisco Division, US v Napoli, et al, October 4, 2012. Matter: Distribution of controlled substances.

Trial: Expert Witness USA Office-Northern District of California, San Francisco Division,
US v Michael Arnold & Jeffrey Herholz, February 16, 2012. Matter: Distribution of controlled substances.

Trial: Expert Witness USA Office-District of Massachusetts, Boston Division, US v Baldwin Ihenacho, January 18, 2012. Matter: Distribution of prescription drugs over the internet.

Trial: Expert Witness USA Office-Eastern District of Texas, Beaumont Division, US v David Vogel, et al, June 30, 2010. Matter: Distribution of prescription drugs over the internet.

Trial: Expert Witness USA Office-Western District of Missouri, Western Division, US v Rostie, et al, June 28, 2010. Matter: Distribution of controlled substances.

Trial: Expert Witness USA Office-Western District of North Carolina, Charlotte Division, US v Woody, et al, August 17, 2009. Matter: Distribution of prescription drugs over the internet.

Trial: Expert Witness USA Office-Middle District of Florida, Orlando Division US v Jude LaCour, et al, April 14, 2009. Matter: Distribution of prescription drugs over the internet.

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Federation of State Medical Boards Award of Merit, 2016

Food and Drug Administration Commissioner's Special Citation, 1994 and 2004

University of Illinois College of Pharmacy Alumni Association Sister Margaret Wright Graduate Award, 2003

American Druggist Magazine, Pharmacist of the Year, 1998

University of Illinois Alumnus of the Year, 1997

Certificate of Appreciation from the Government of the District of Columbia, 1990

Member of the National Pharmacy Honor Society, Rho Chi, 1983–1987

Affiliations:

Registered Pharmacist, Illinois

Chair, Pharmacy Technician Certification Board Certification Council

Governor, Board of Governors, Pharmacy Technician Certification Board

Member, Board of Directors, Federation of Association of Regulatory Boards

Member, Board of Directors, American Foundation for Pharmaceutical Education

Instructor, Drug Enforcement Administration Training Academy 2008 - Current

Delegate, United States Pharmacopeia Convention, Inc

Member, American Institute of the History of Pharmacy

Member, American Pharmacist Association

Member, American Society for Pharmacy Law

Member, American Society of Health System Pharmacists

Member, American Society for Automation in Pharmacy

Member, Board of Trustees, United States Pharmacopeia, 2005-2007

Member, National Conference Pharmaceutical Organizations, 2006

Adjunct Member, Dept of Pharmacy Administration, University of Illinois at Chicago, 1991-1999

Member, Board of Directors, University of Illinois Alumni Association, 1992–1995

President, National Drug Trade Conference, 1995